

(12) **UK Patent Application** (19) **GB** (11) **2 360 461** (13) **A**

(43) Date of A Publication 26.09.2001

(21) Application No 0030974.0

(22) Date of Filing 19.12.2000

(30) Priority Data

(31) 0007085

(32) 23.03.2000

(33) GB

(31) 0009491

(32) 17.04.2000

(71) Applicant(s)

Photo-Therapeutics Ltd
(Incorporated in the United Kingdom)
Station House, Stamford New Road,
Station Business Centre, ALTRINGHAM, Cheshire,
WA14 1EP, United Kingdom

(72) Inventor(s)

Colin Whitehurst

(74) Agent and/or Address for Service

R.G.C.Jenkins & Co
26 Caxton Street, LONDON, SW1H 0RJ,
United Kingdom

(51) INT CL⁷

A61N 5/06

(52) UK CL (Edition S)

A5R REHR

(56) Documents Cited

EP 0266038 A

WO 99/19024 A

WO 98/43704 A

WO 01/14012 A

WO 00/15296 A

US 5616140 A

(58) Field of Search

UK CL (Edition S) A5R REHR

INT CL⁷ A61N 5/06

ONLINE: EPODOC, WPI, JAPIO

(54) Abstract Title

Therapeutic light source and method

(57) A therapeutic light source, for example for photodynamic therapy (PDT), comprises comprising an array of preferably independently switchable red and blue light-emitting diodes L_R , L_B , mounted on a flexible backing.

Other arrangements of non-planar arrays of LEDs are also claimed, both for external and internal use as well as light sources comprising LEDs having specific emission wavelengths.

FIG. 26

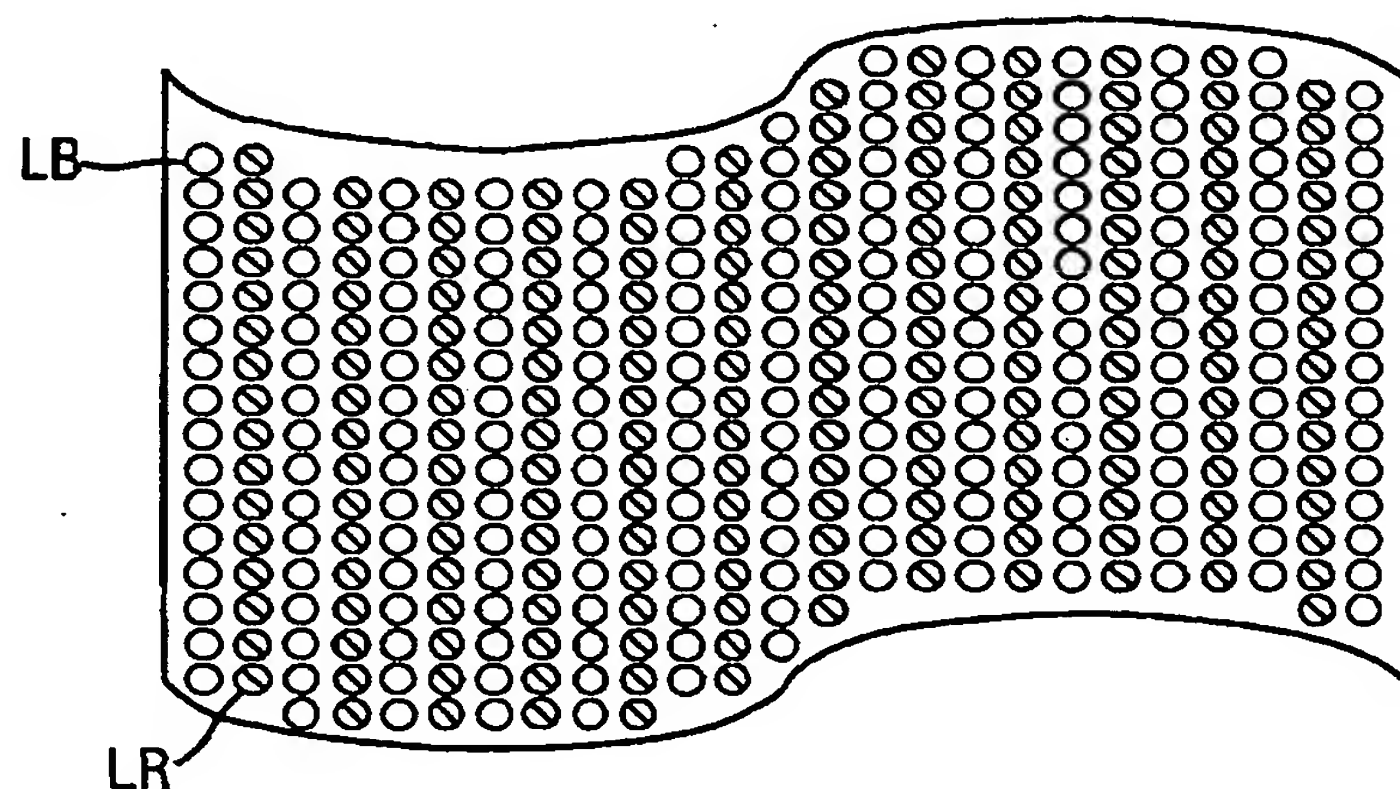


FIG. 1

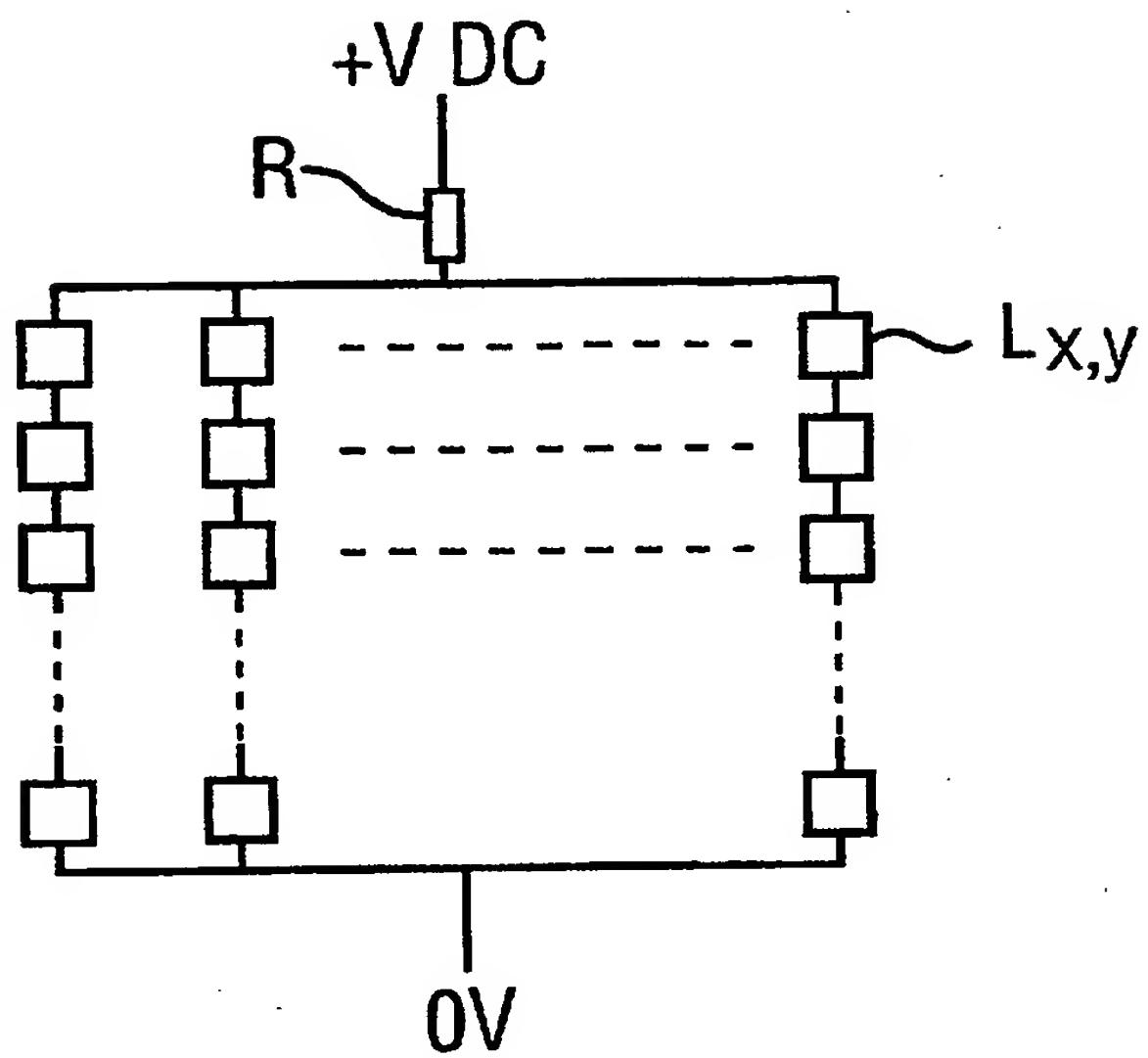


FIG. 5

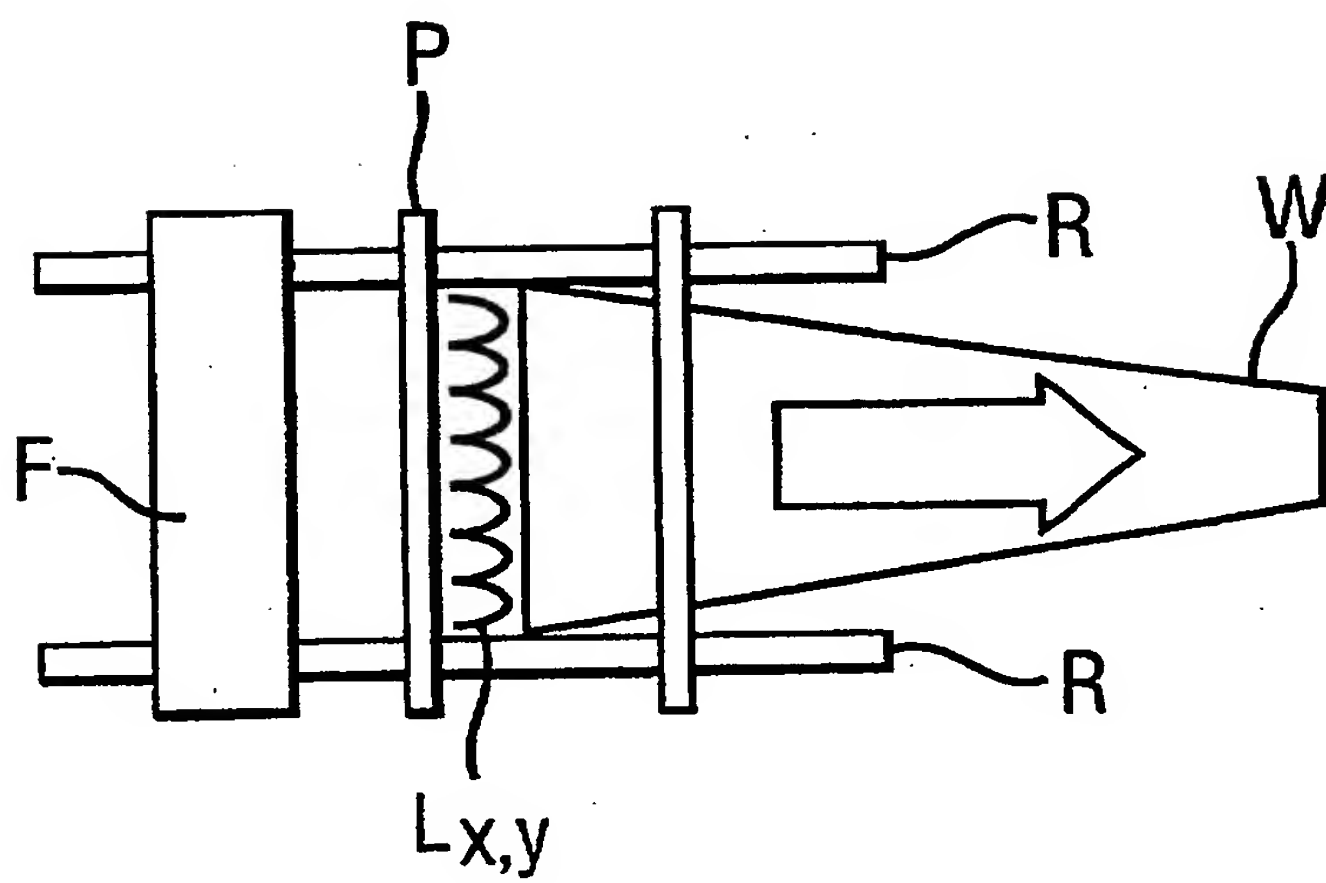


FIG. 2

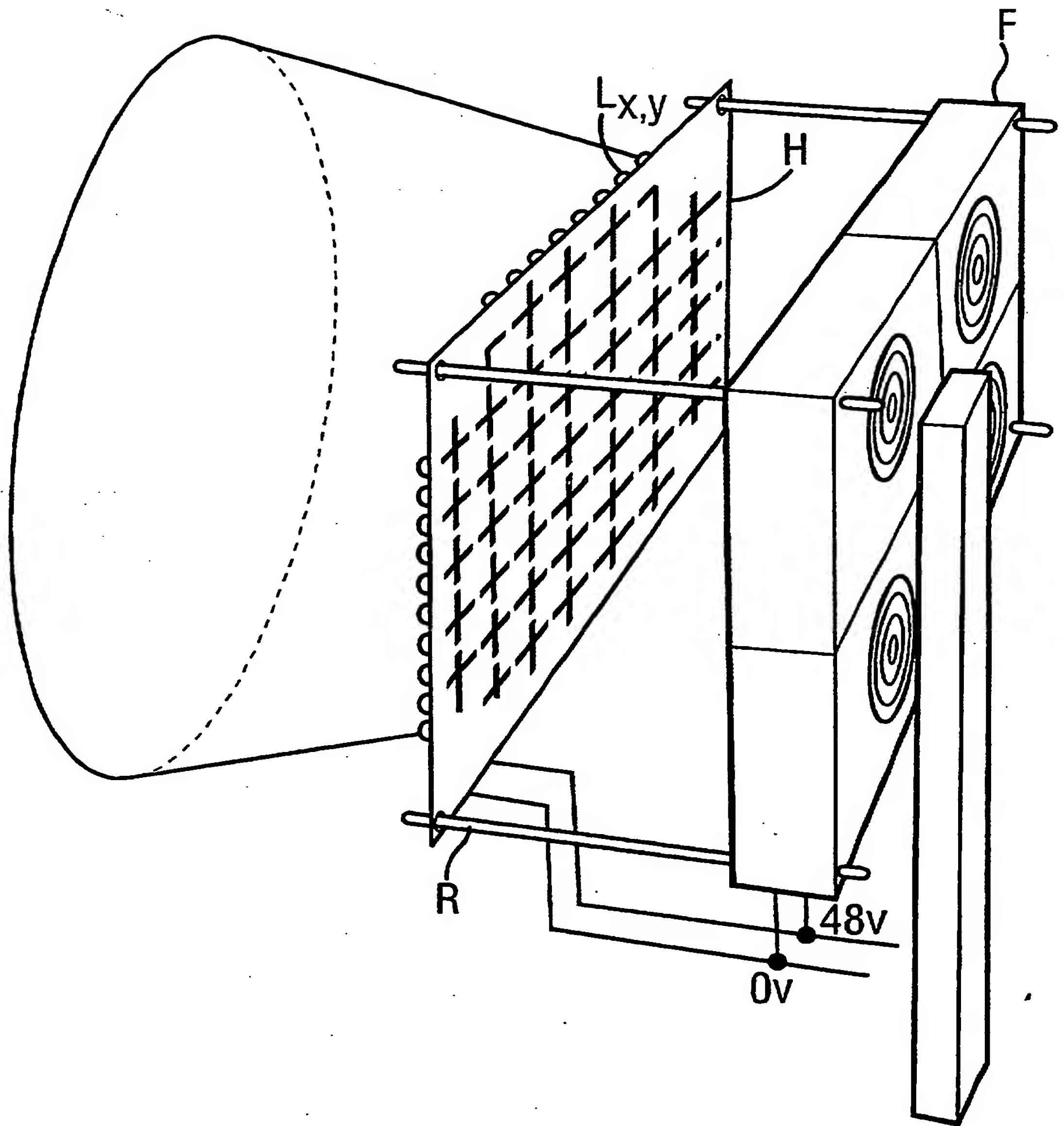


FIG. 3

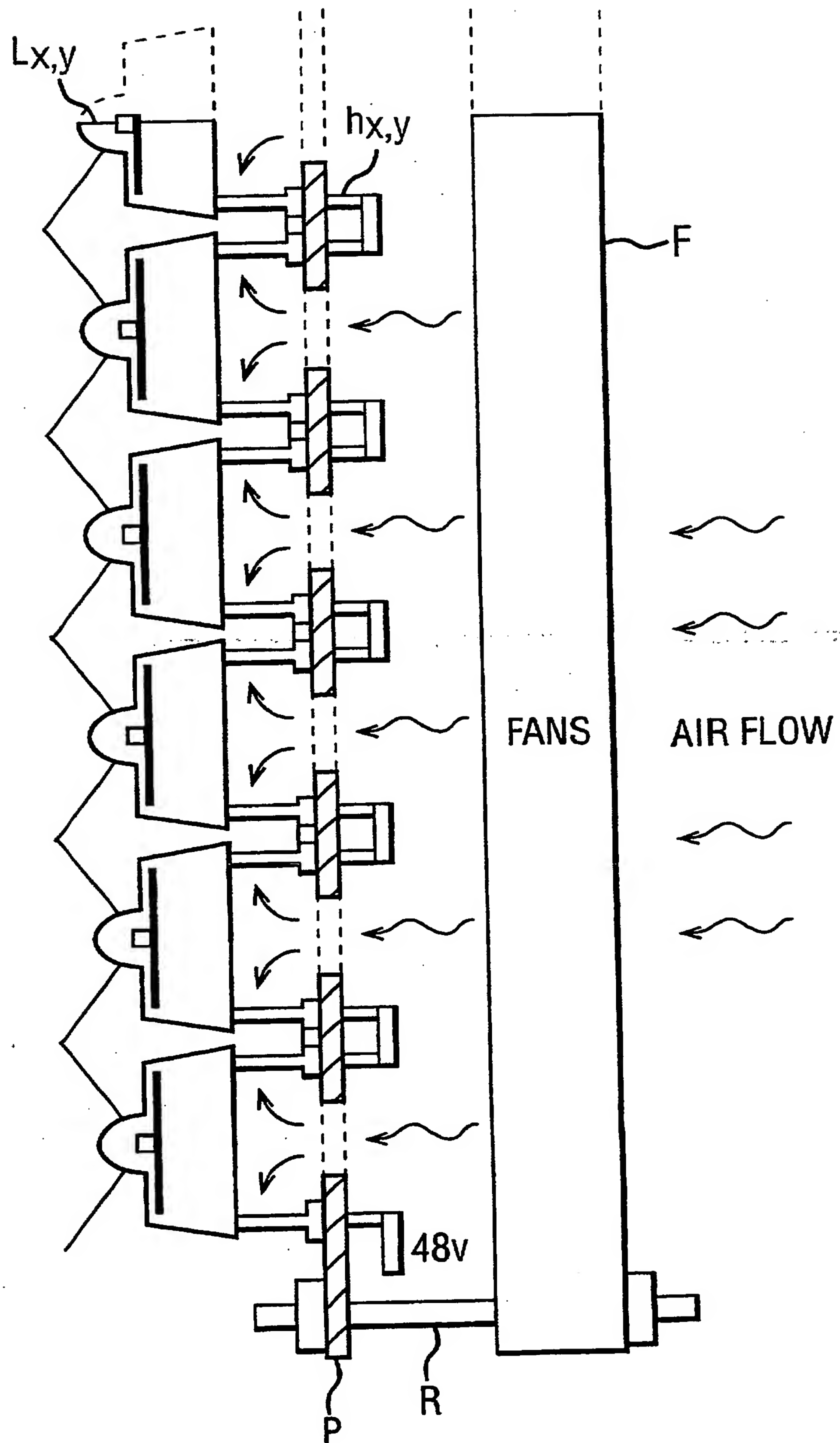


FIG. 4

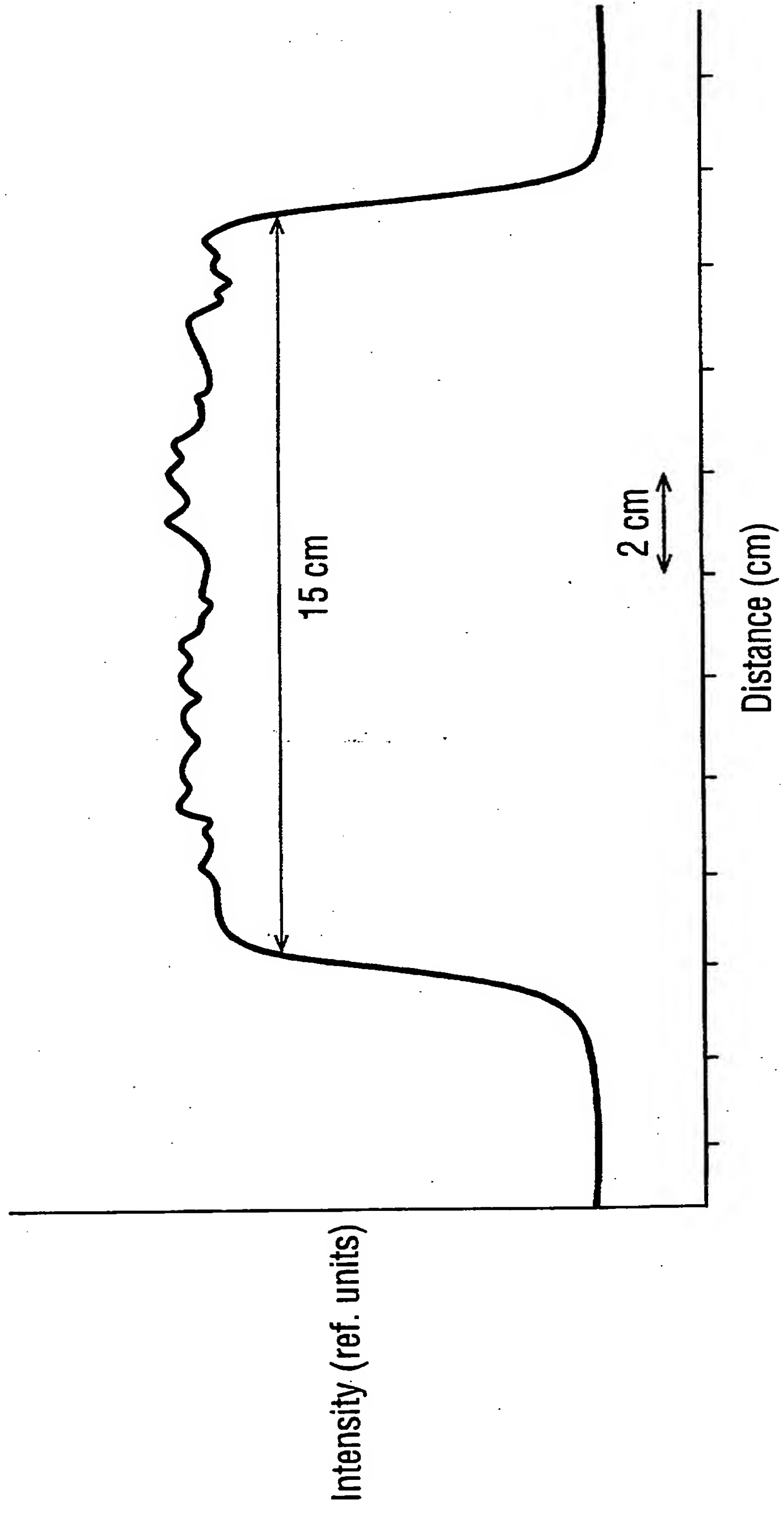


FIG. 6

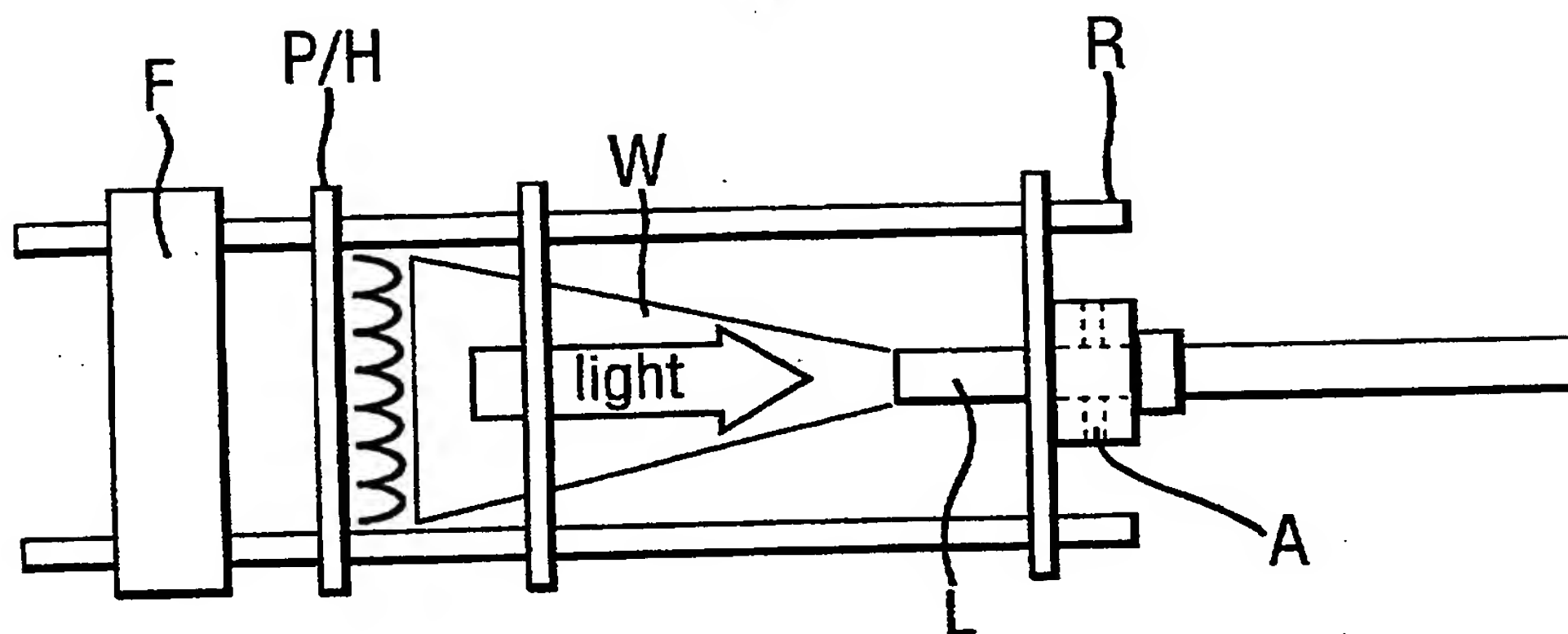


FIG. 7

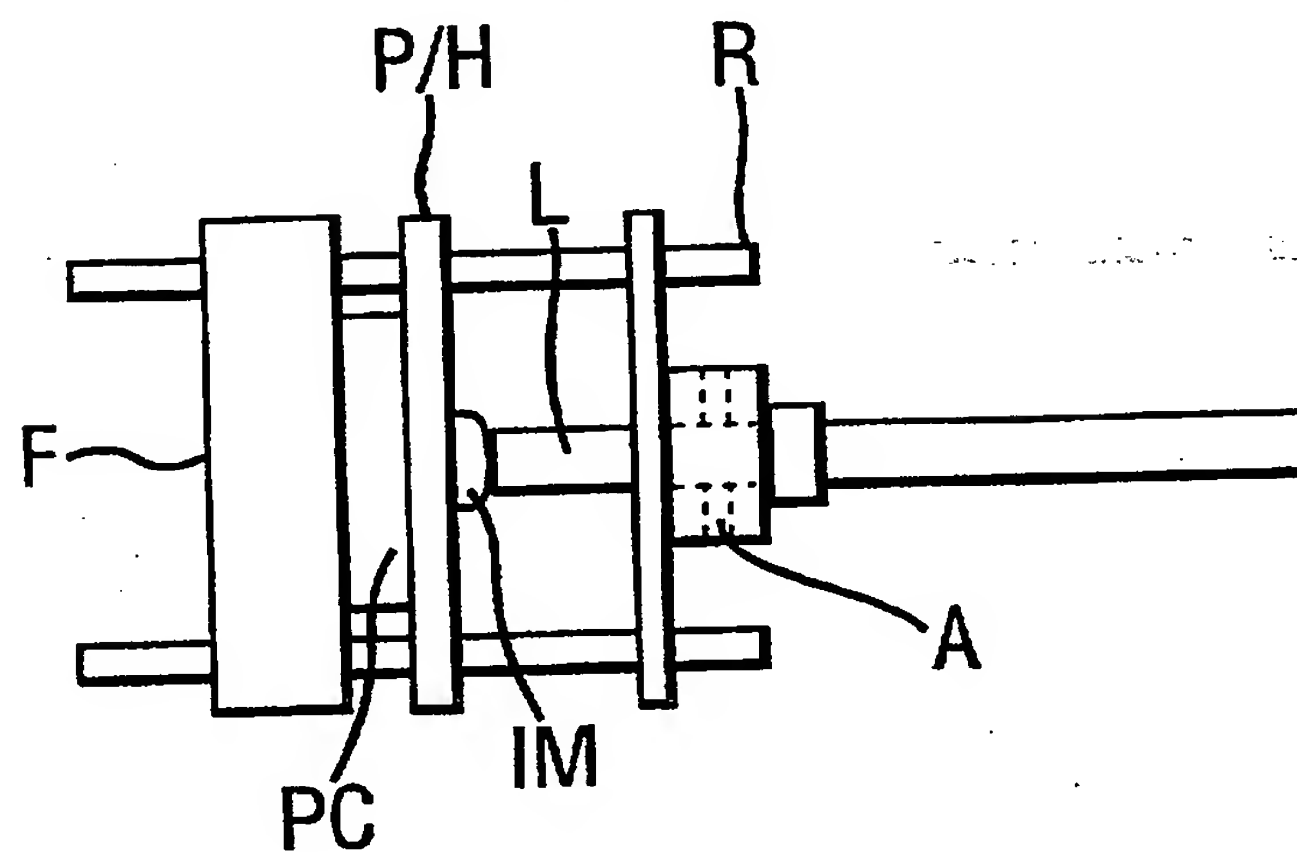


FIG. 8

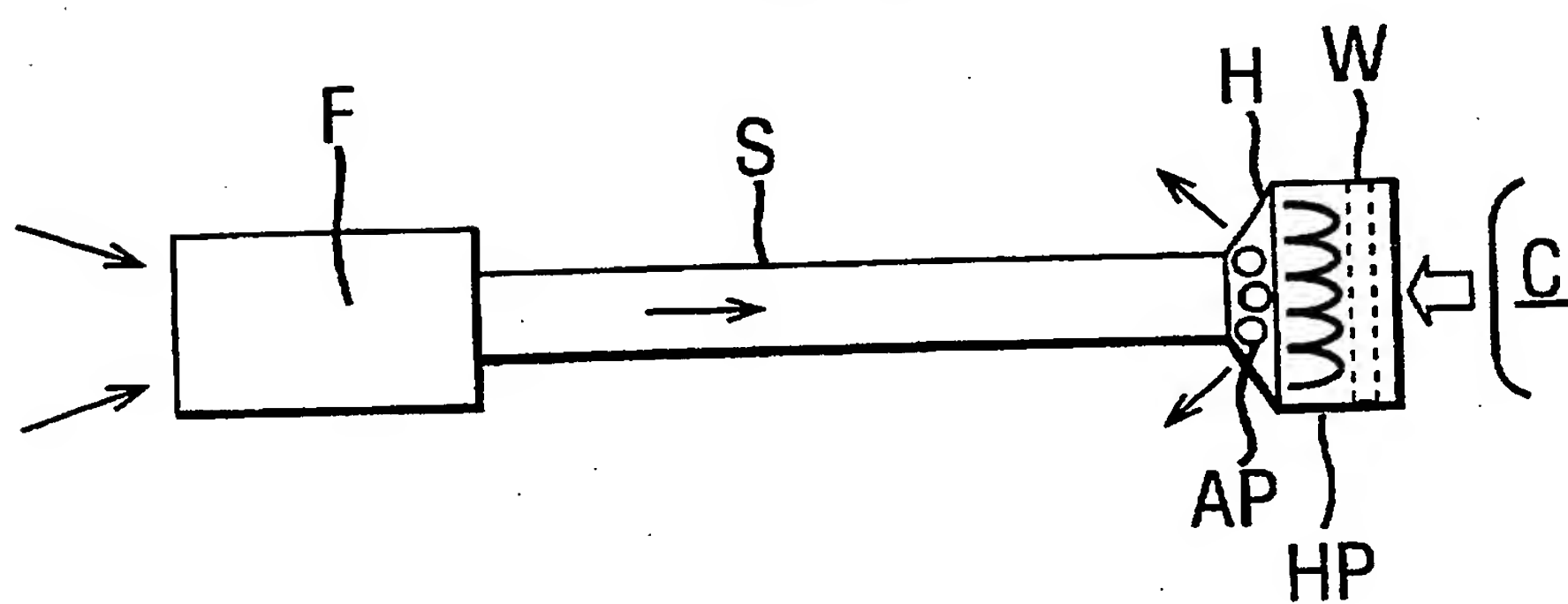


FIG. 9

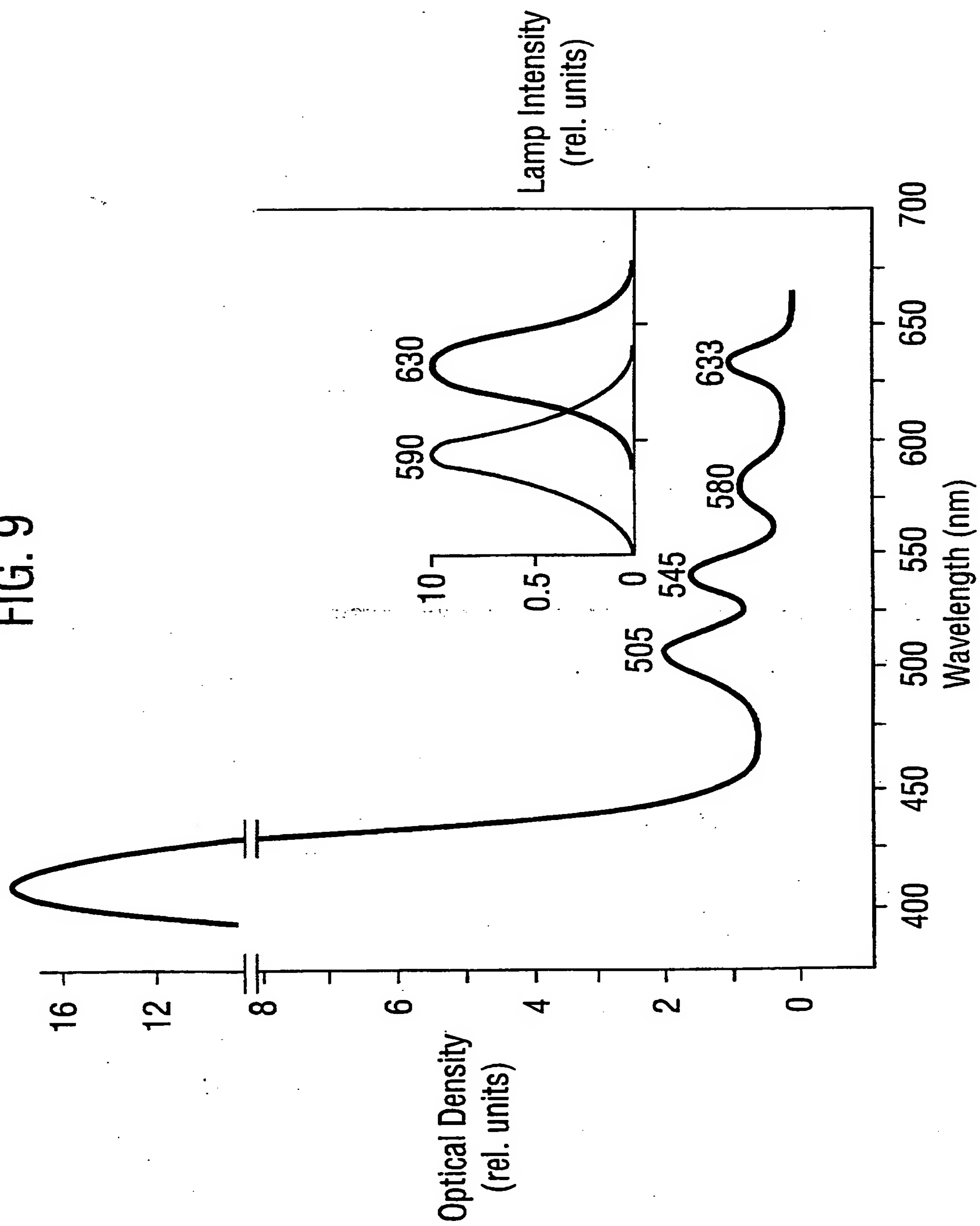


FIG. 10a

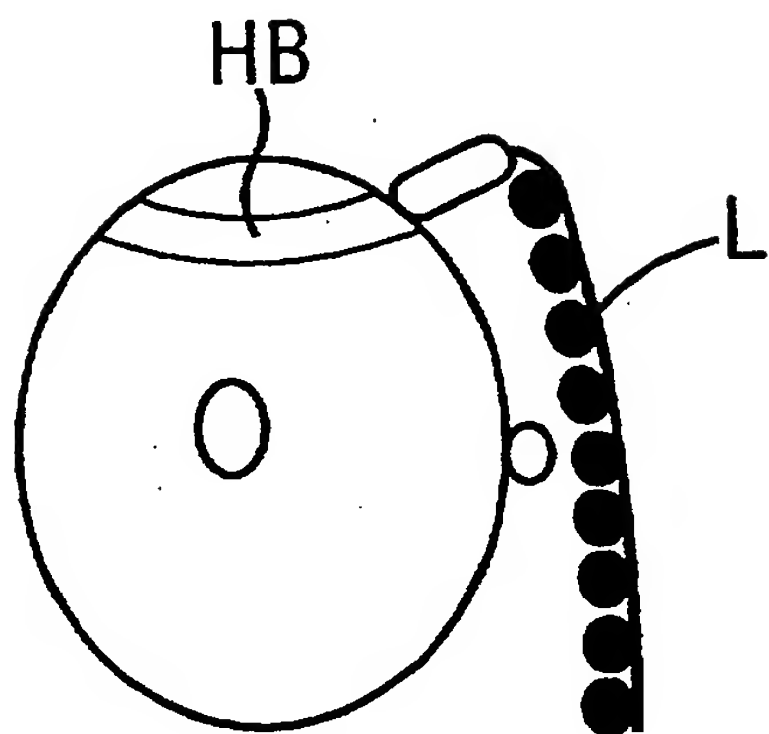


FIG. 10b

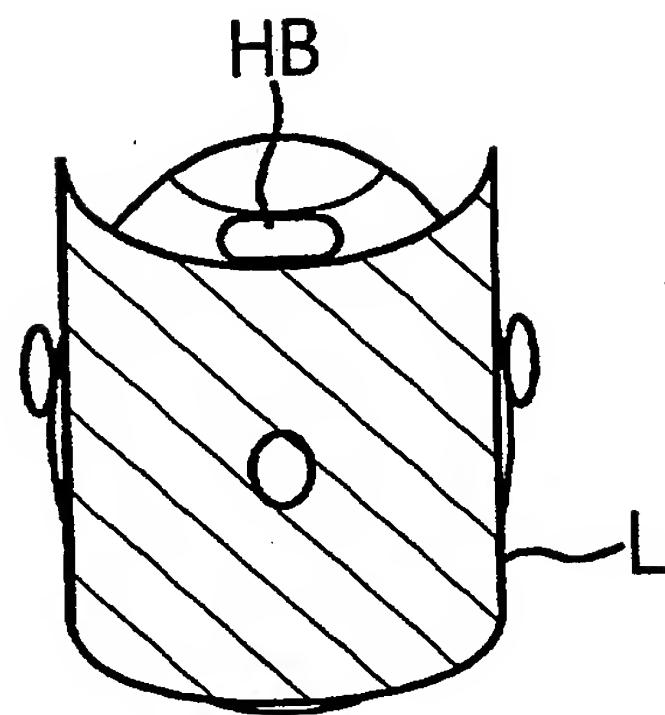


FIG. 11a

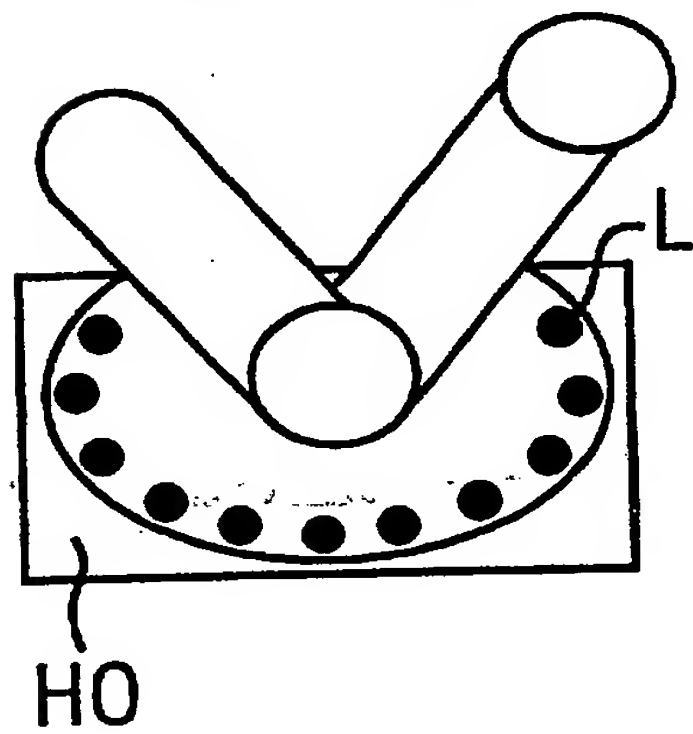


FIG. 11b

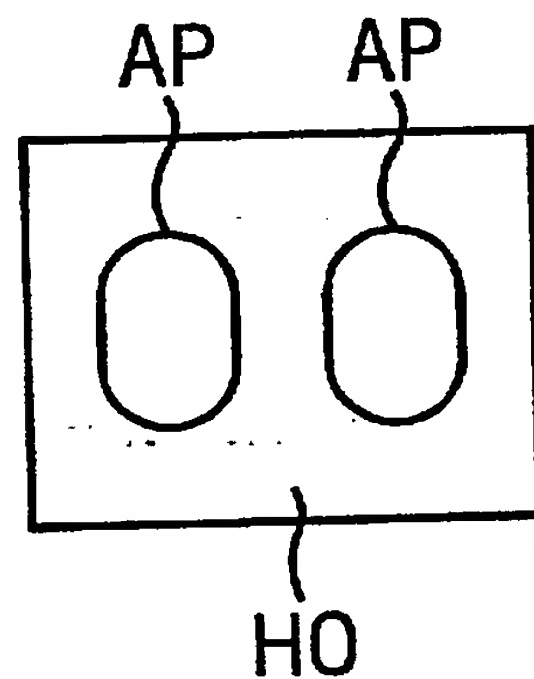


FIG. 11c

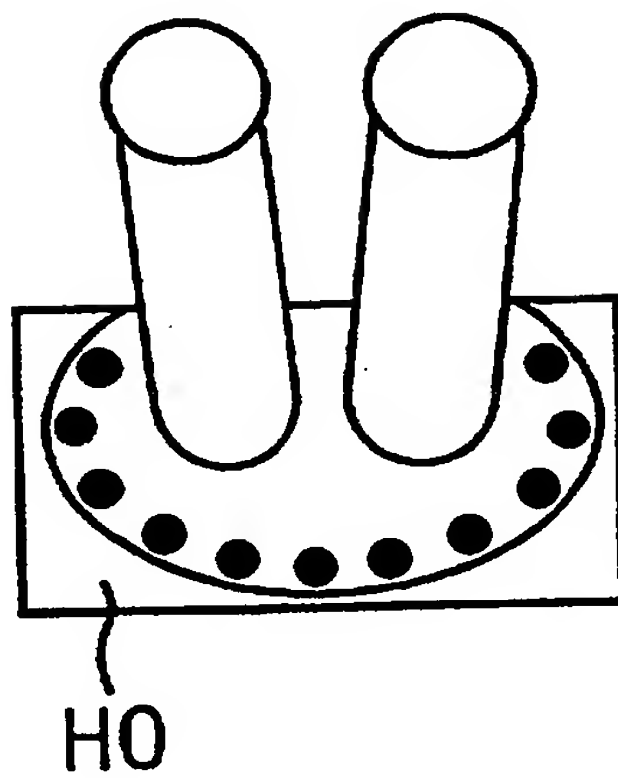


FIG. 12

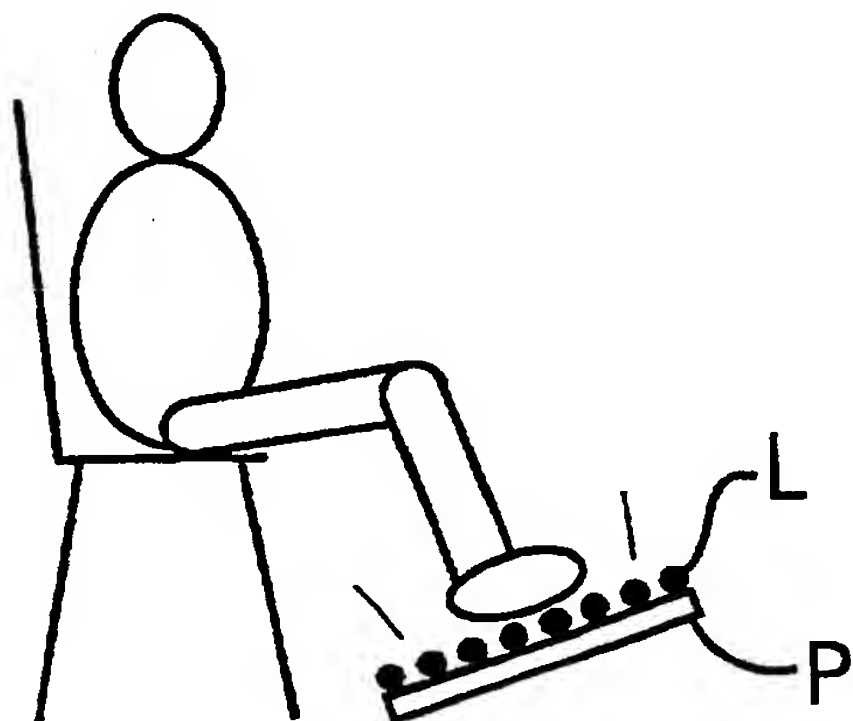


FIG. 13

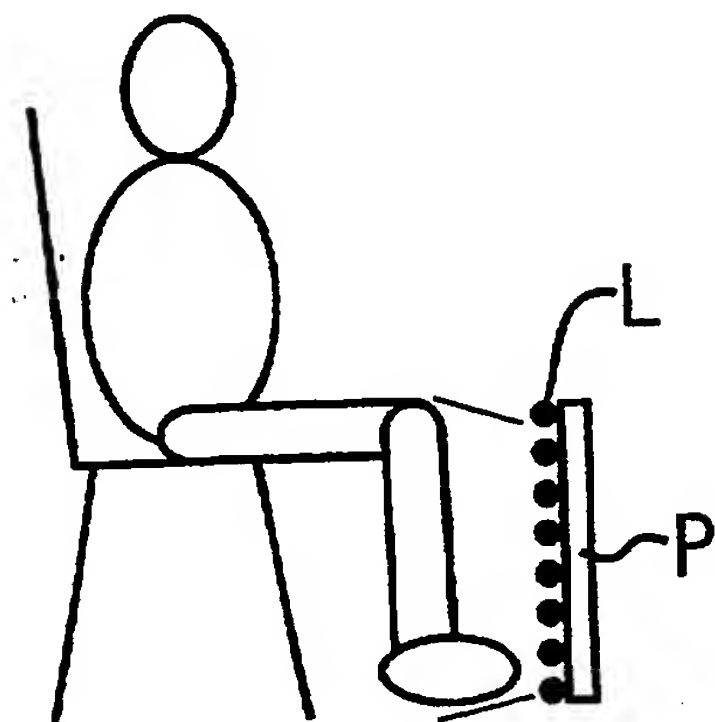


FIG. 14

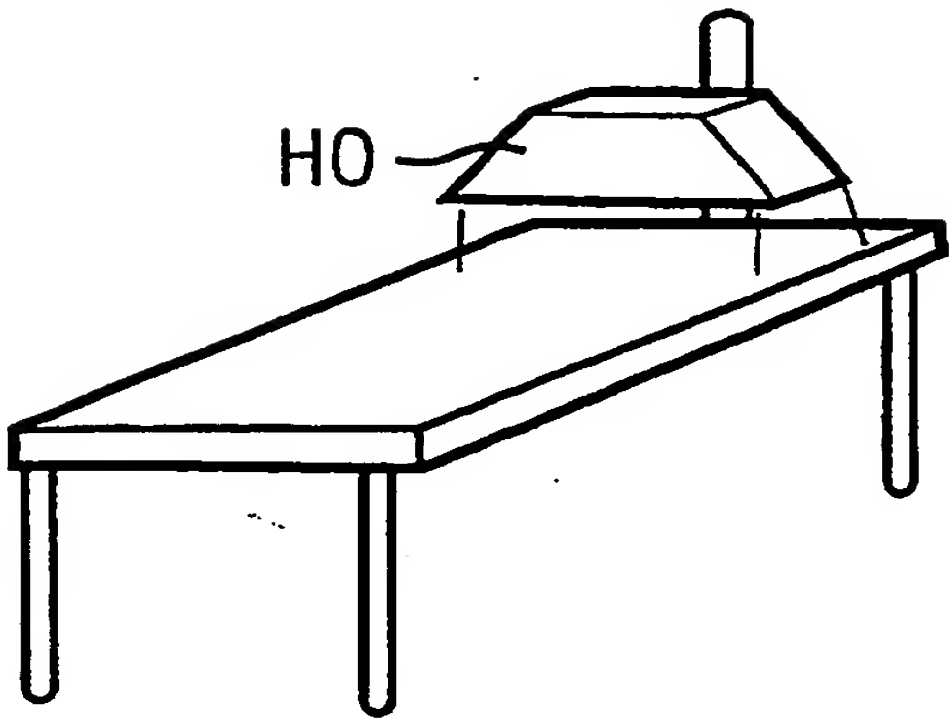


FIG. 15

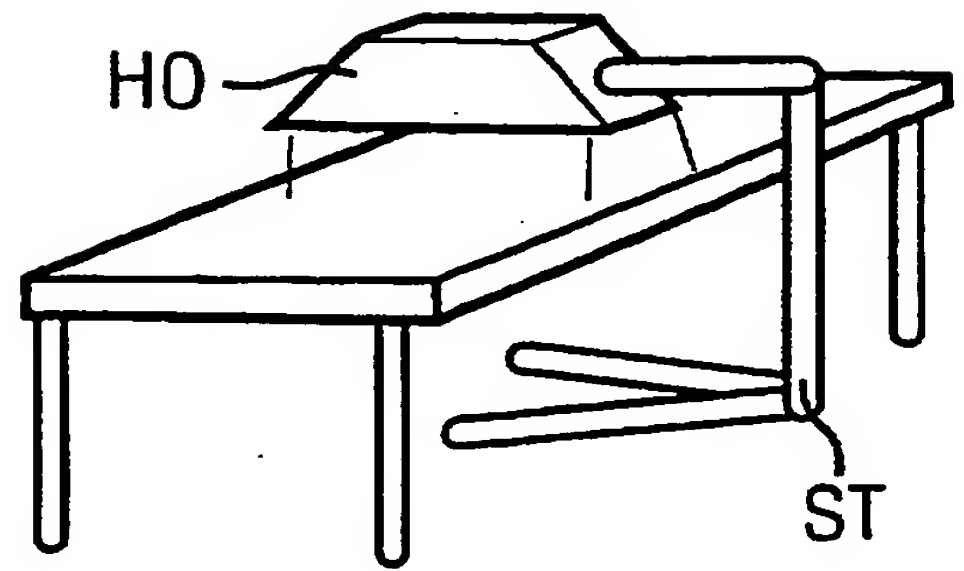


FIG. 16a

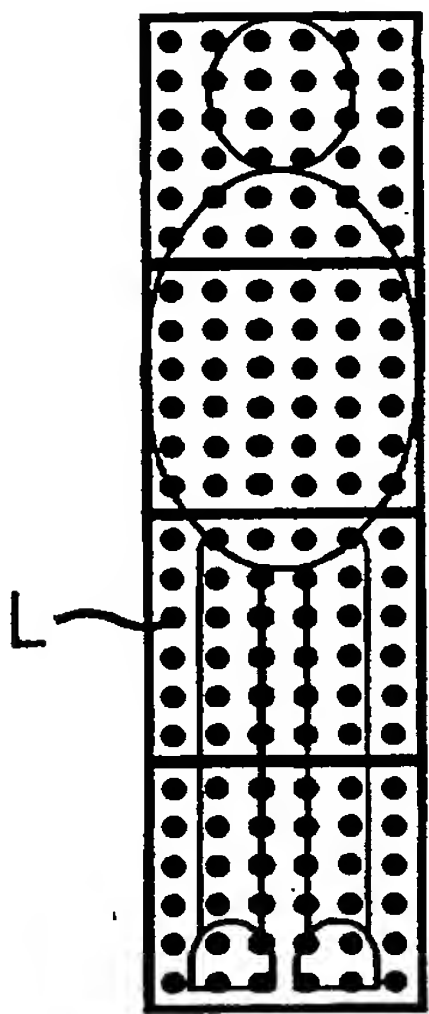


FIG. 16b

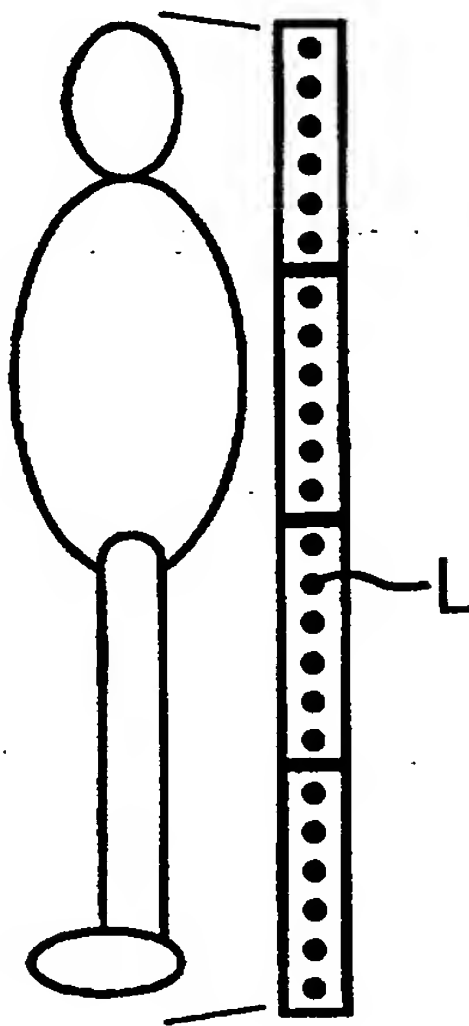


FIG. 17a

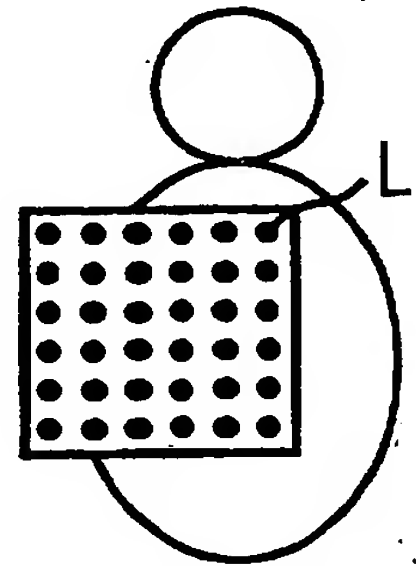


FIG. 17b

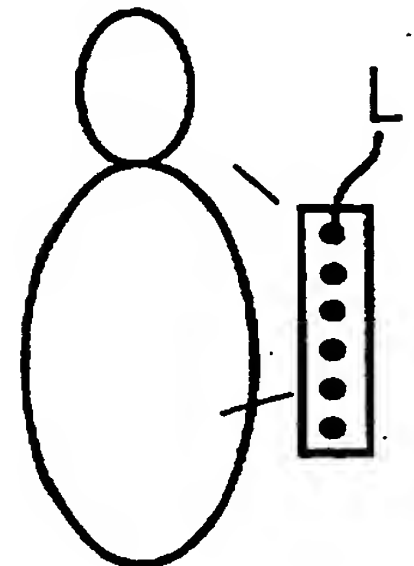


FIG. 18a

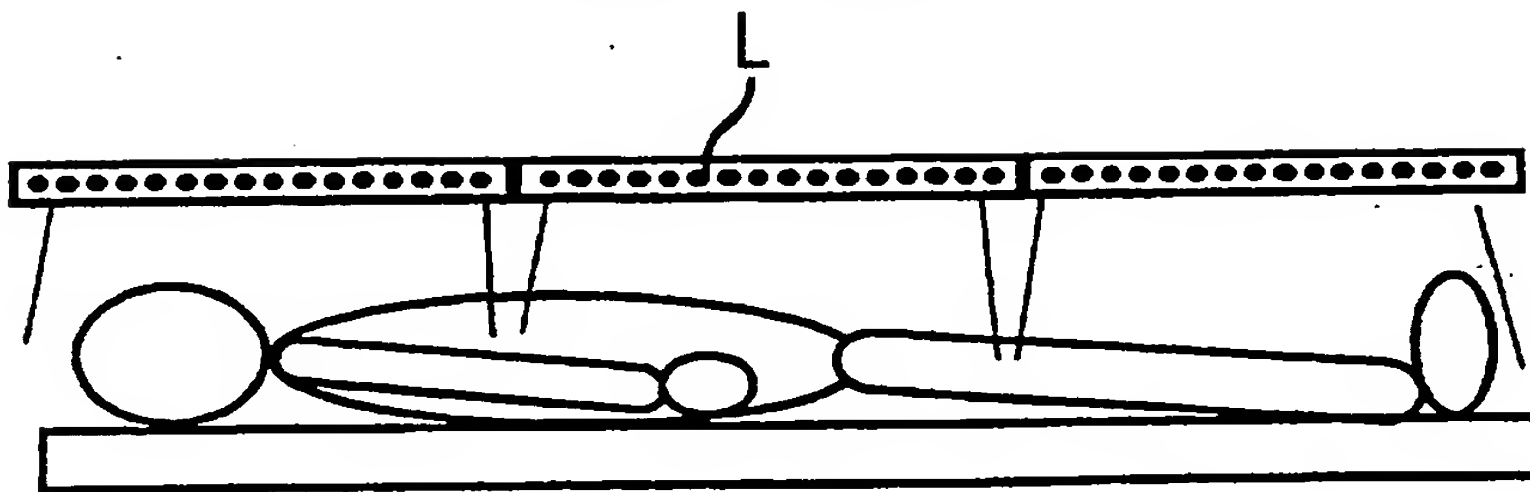


FIG. 18b

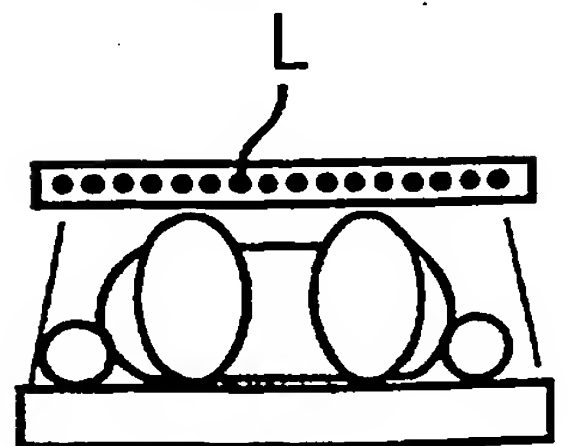


FIG. 19a

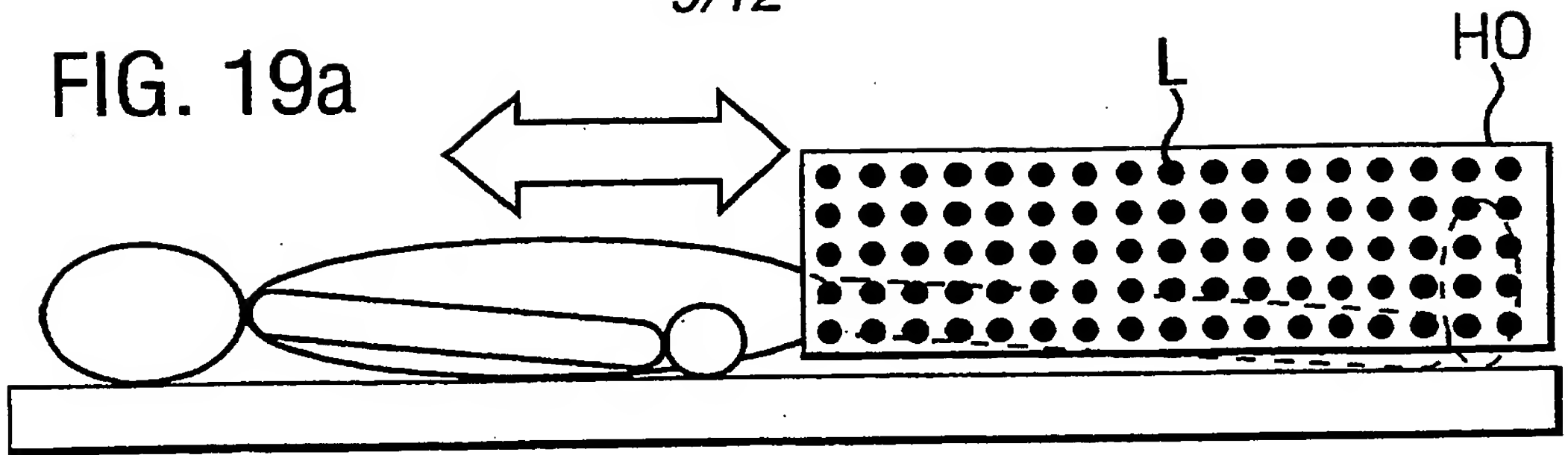


FIG. 19b

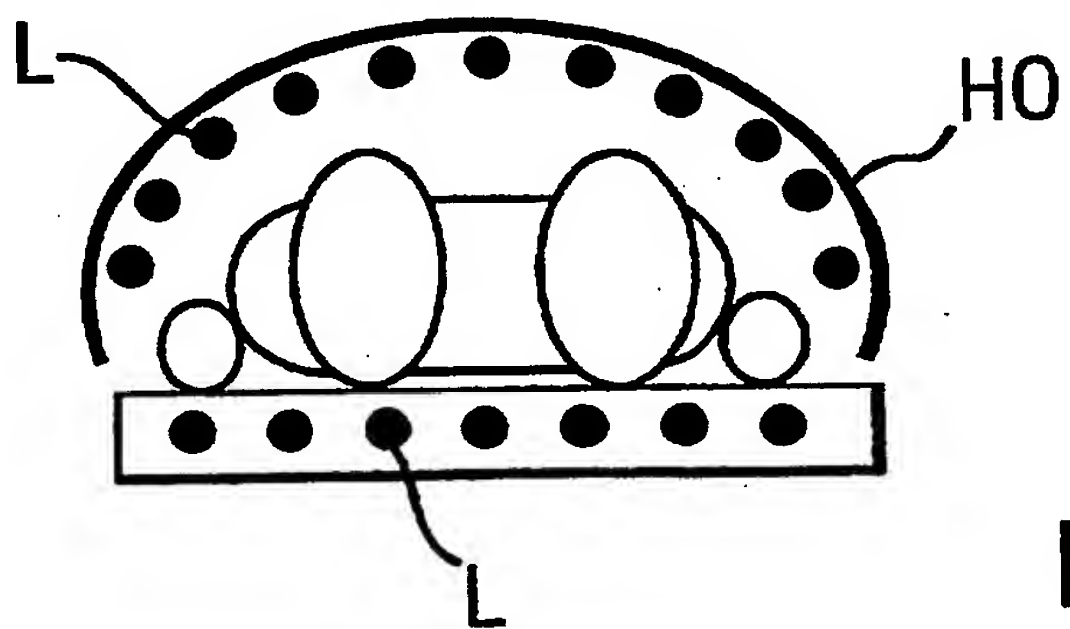


FIG. 20a

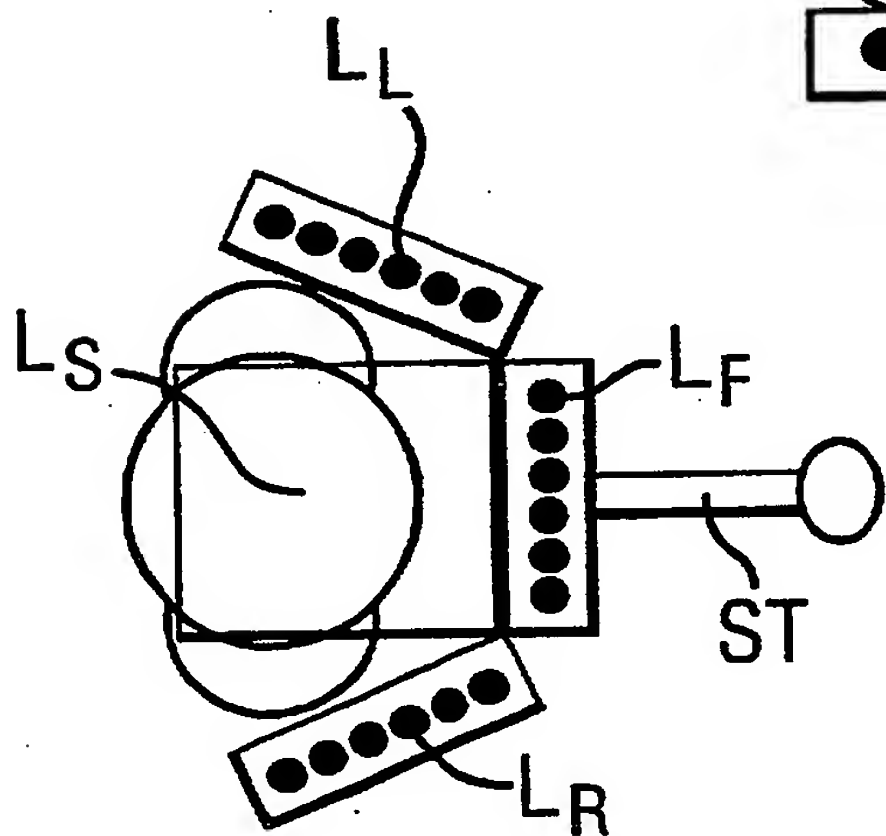


FIG. 20b

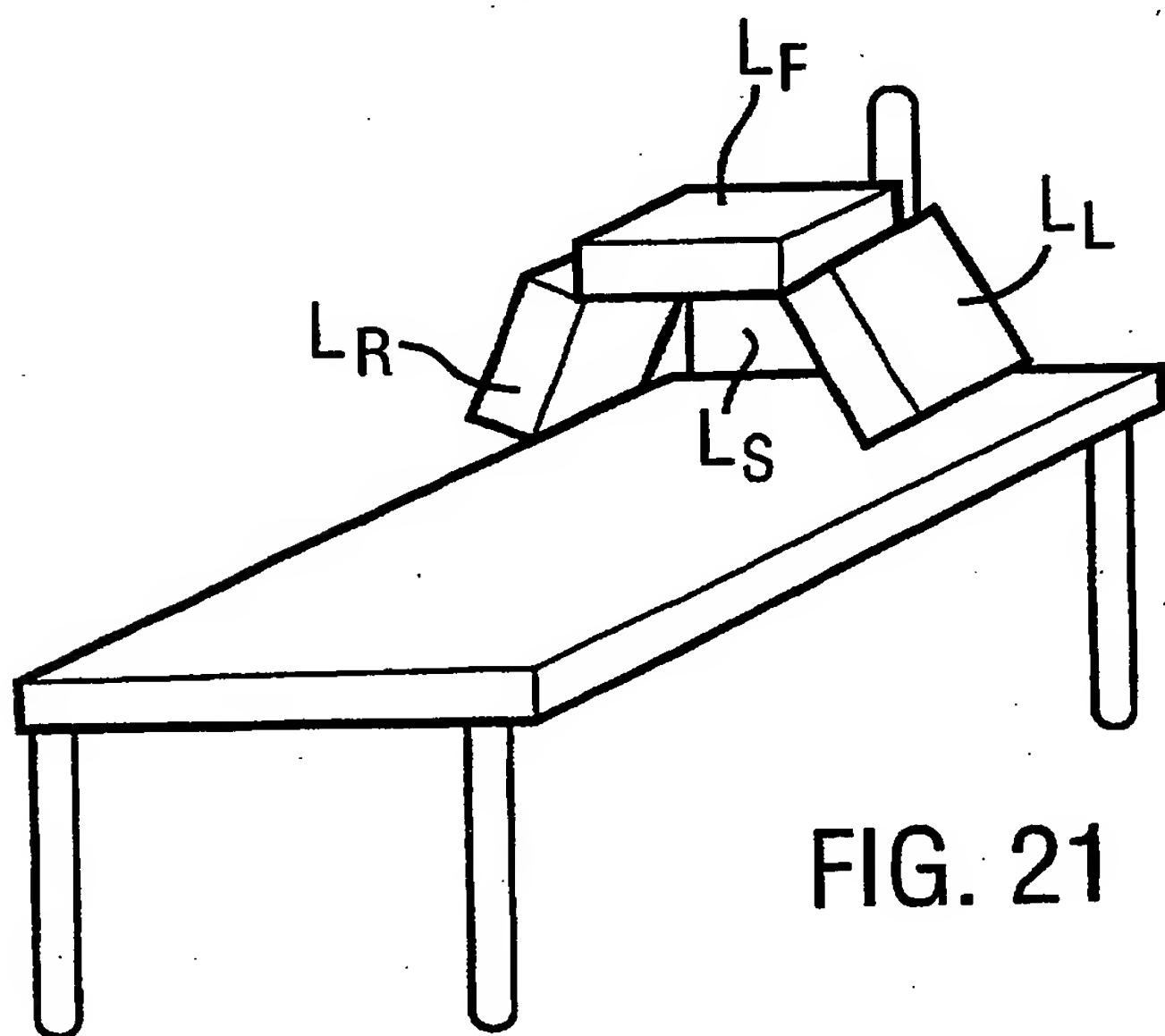
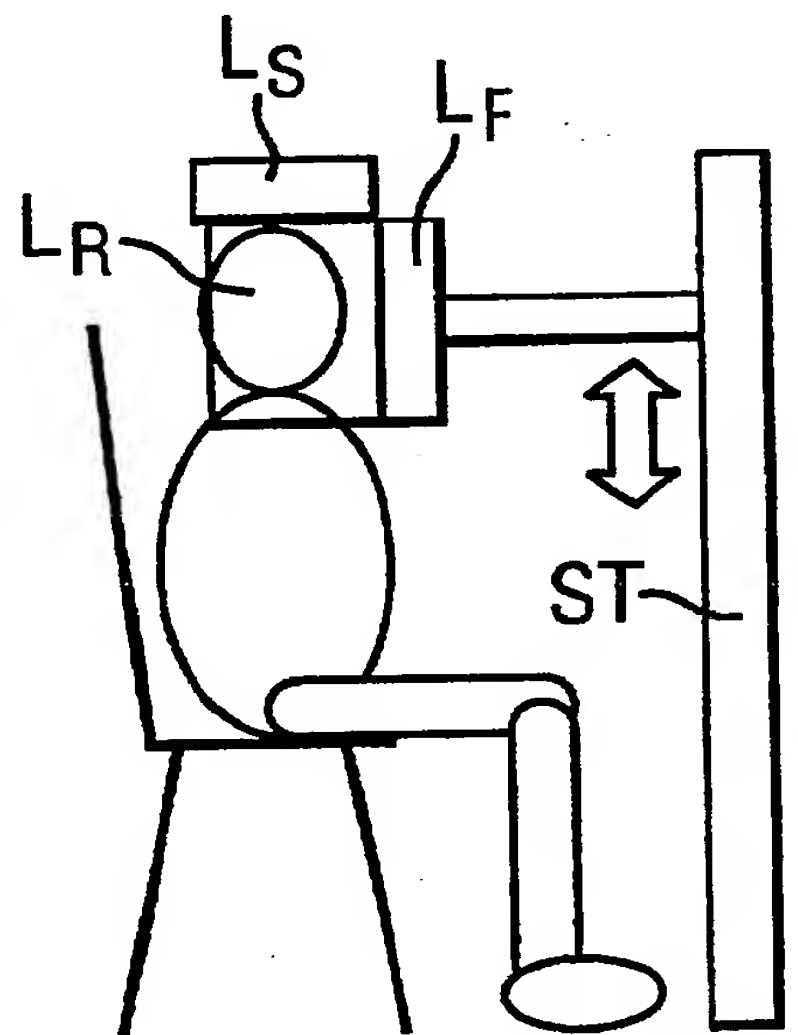


FIG. 21

FIG. 22a

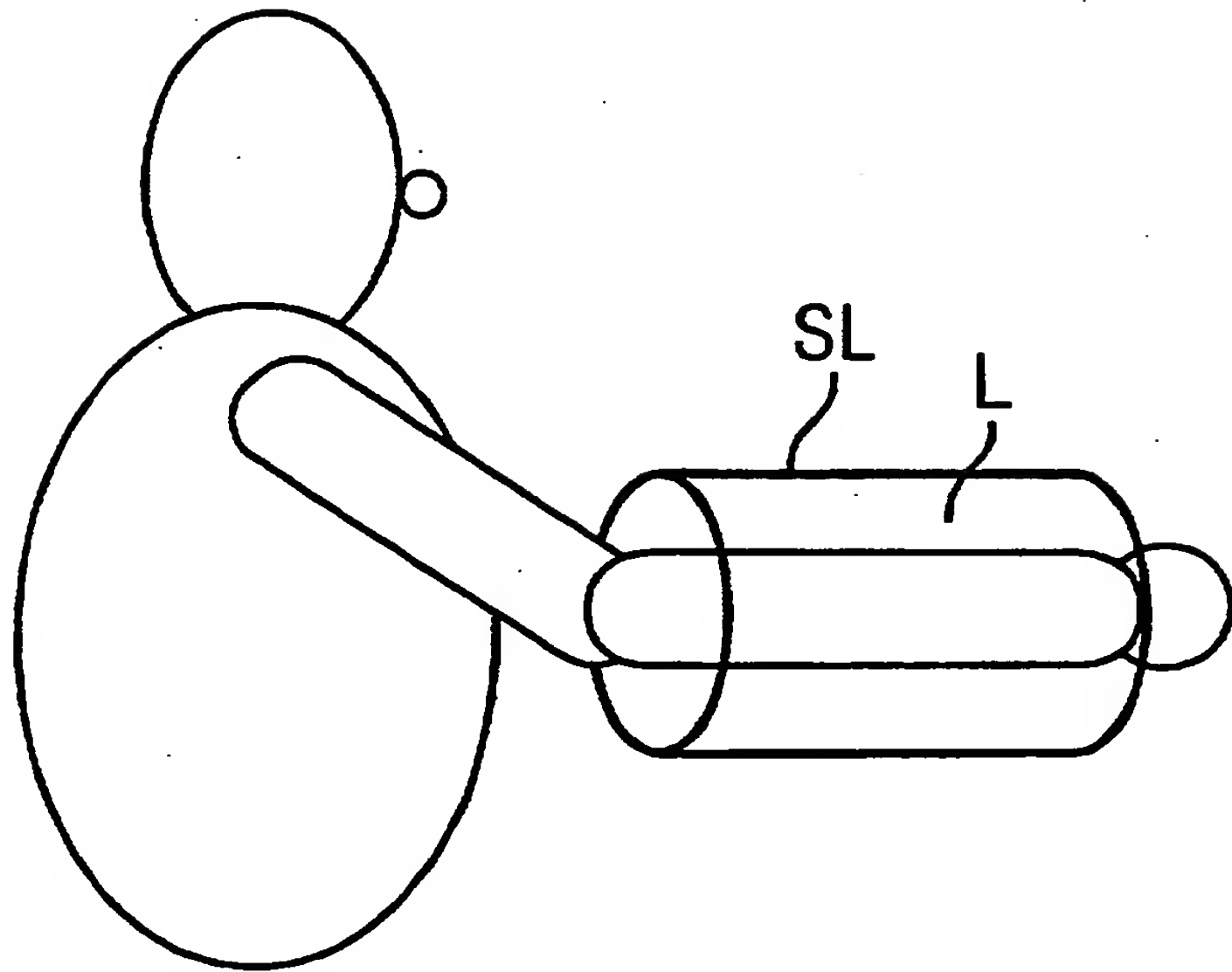


FIG. 22b

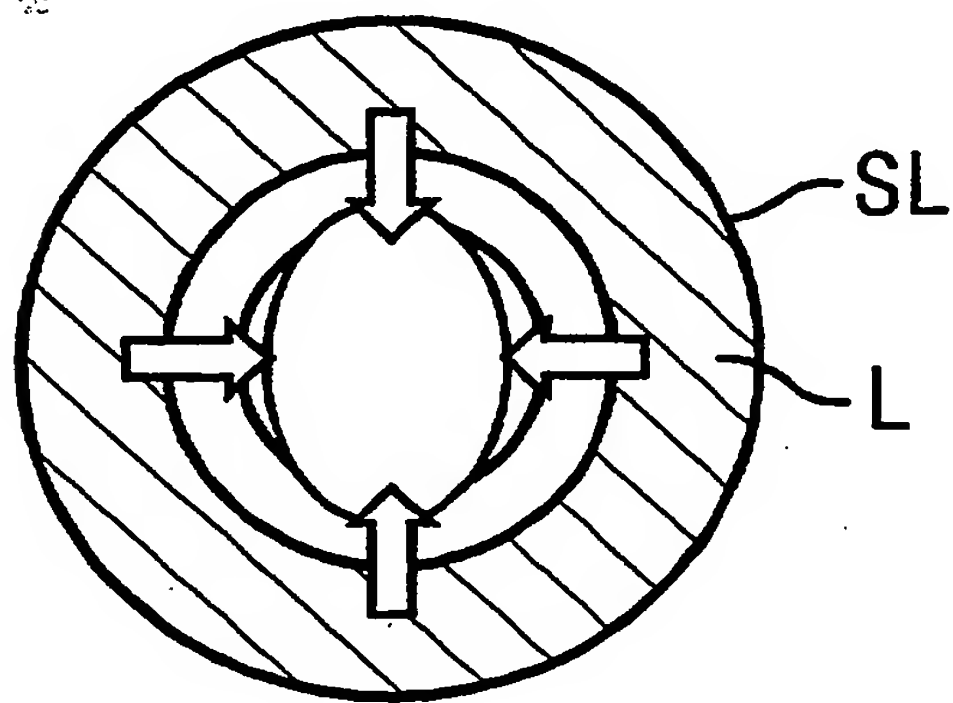


FIG. 22c

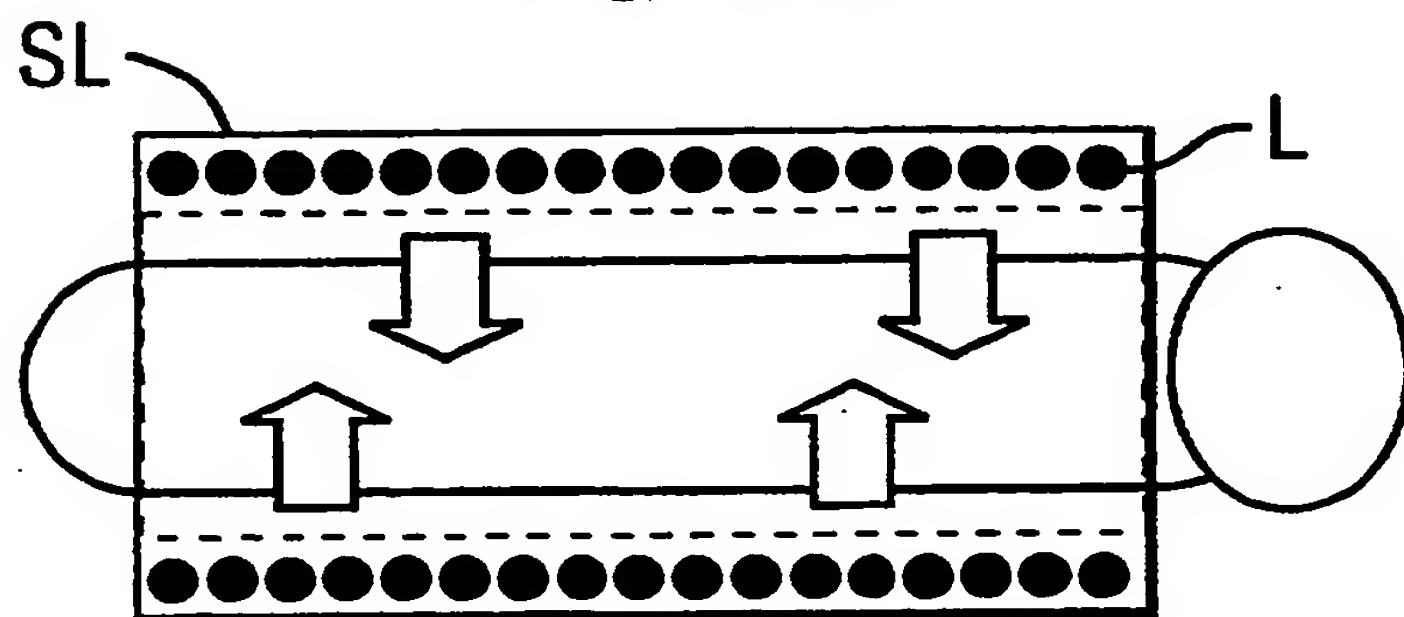


FIG. 23a

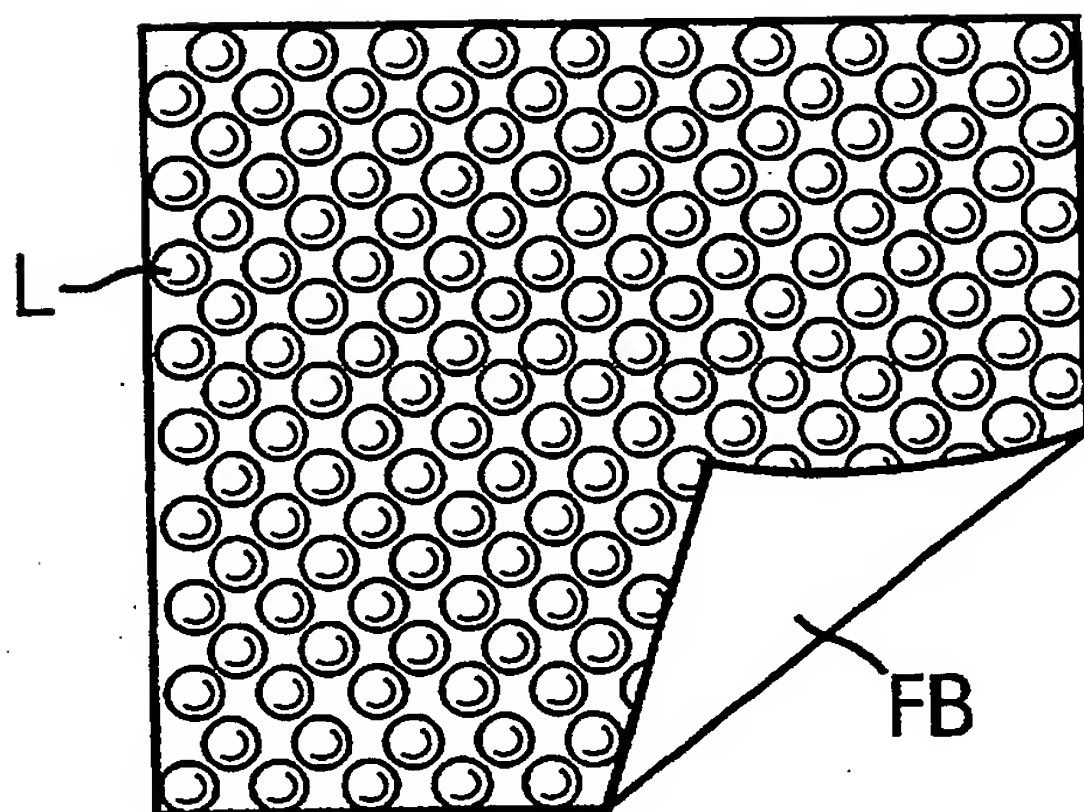


FIG. 23b

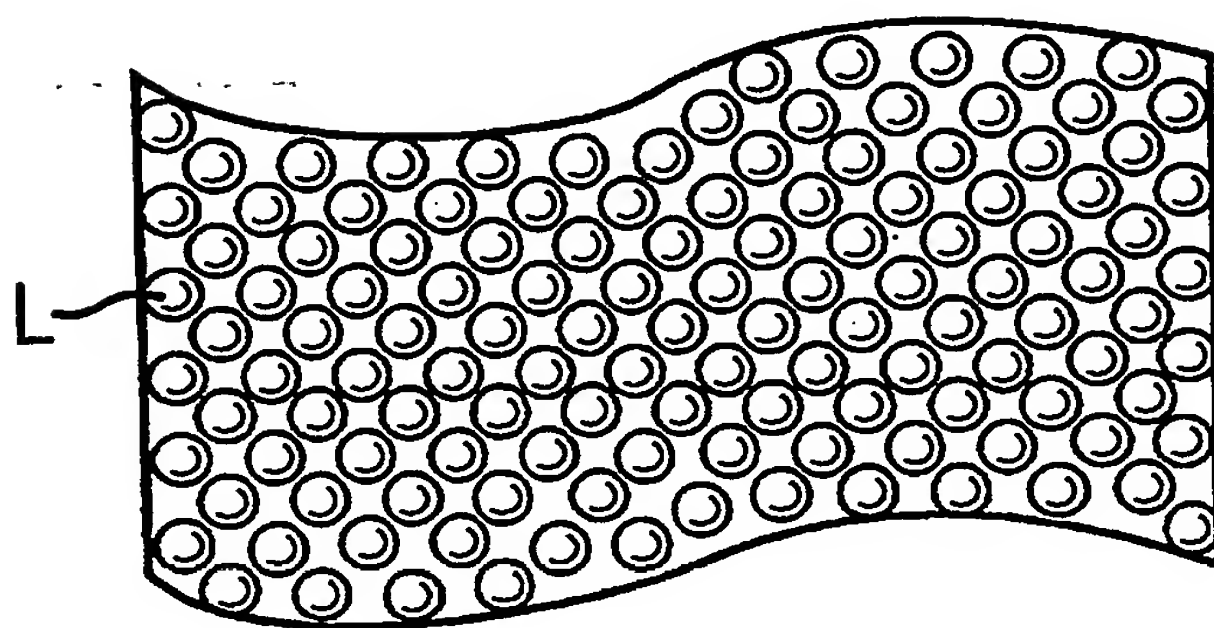


FIG. 23c

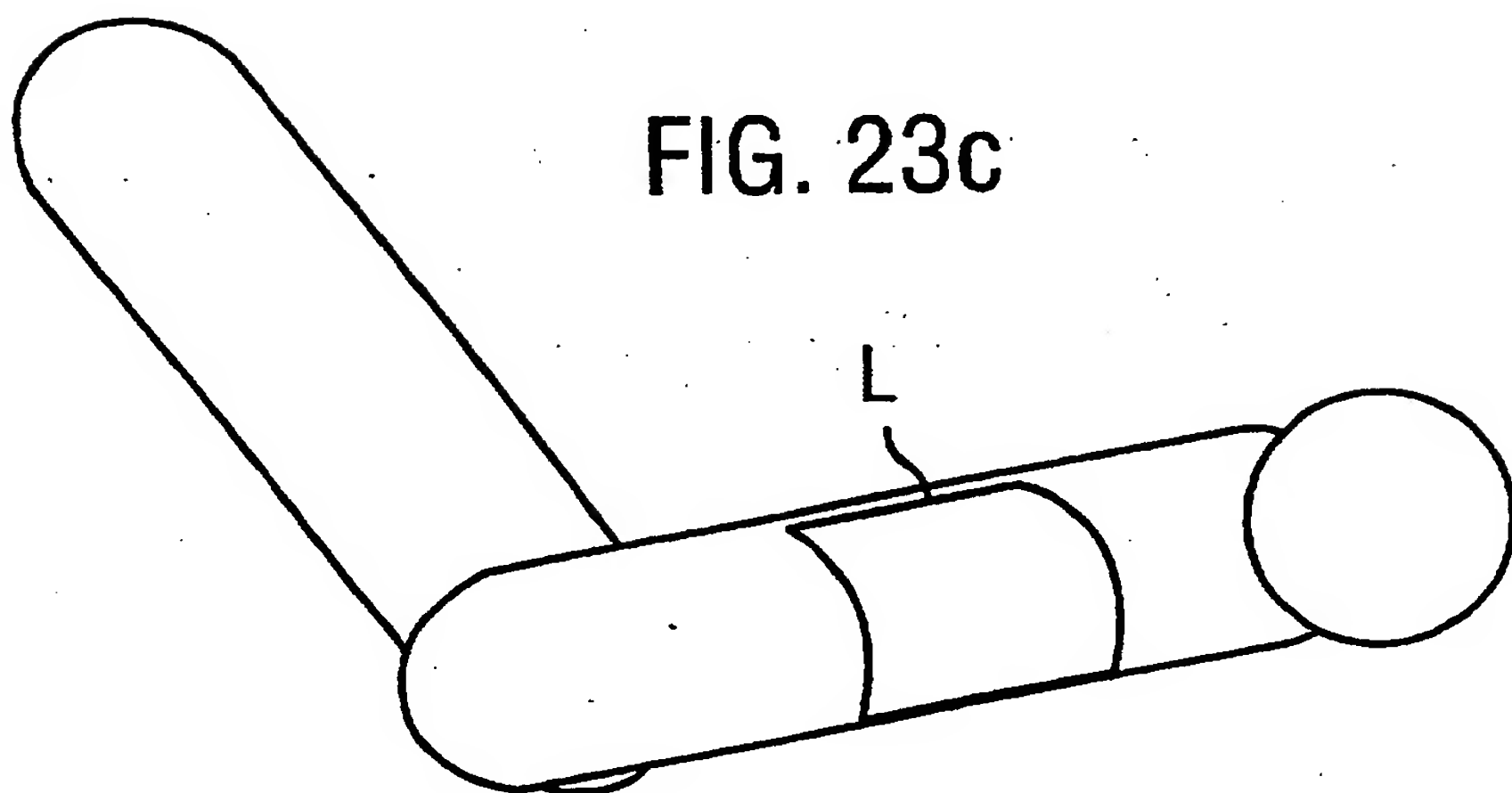


FIG. 24

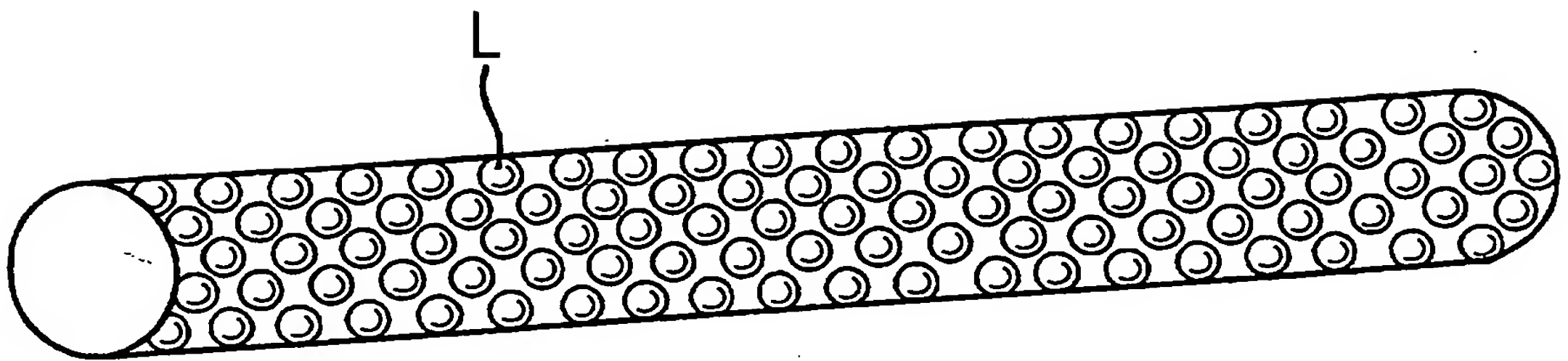


FIG. 25

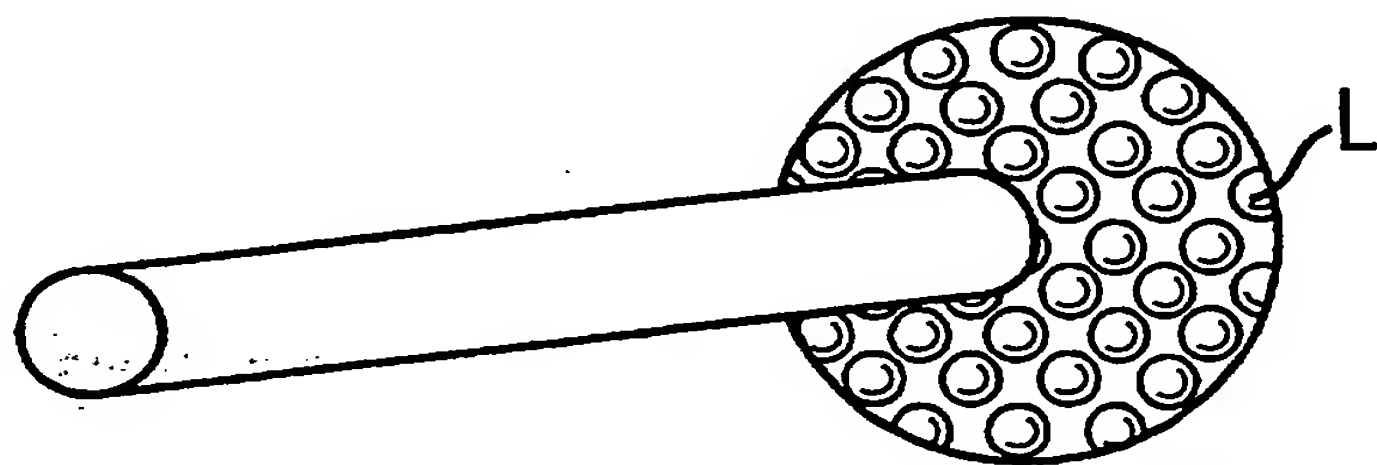
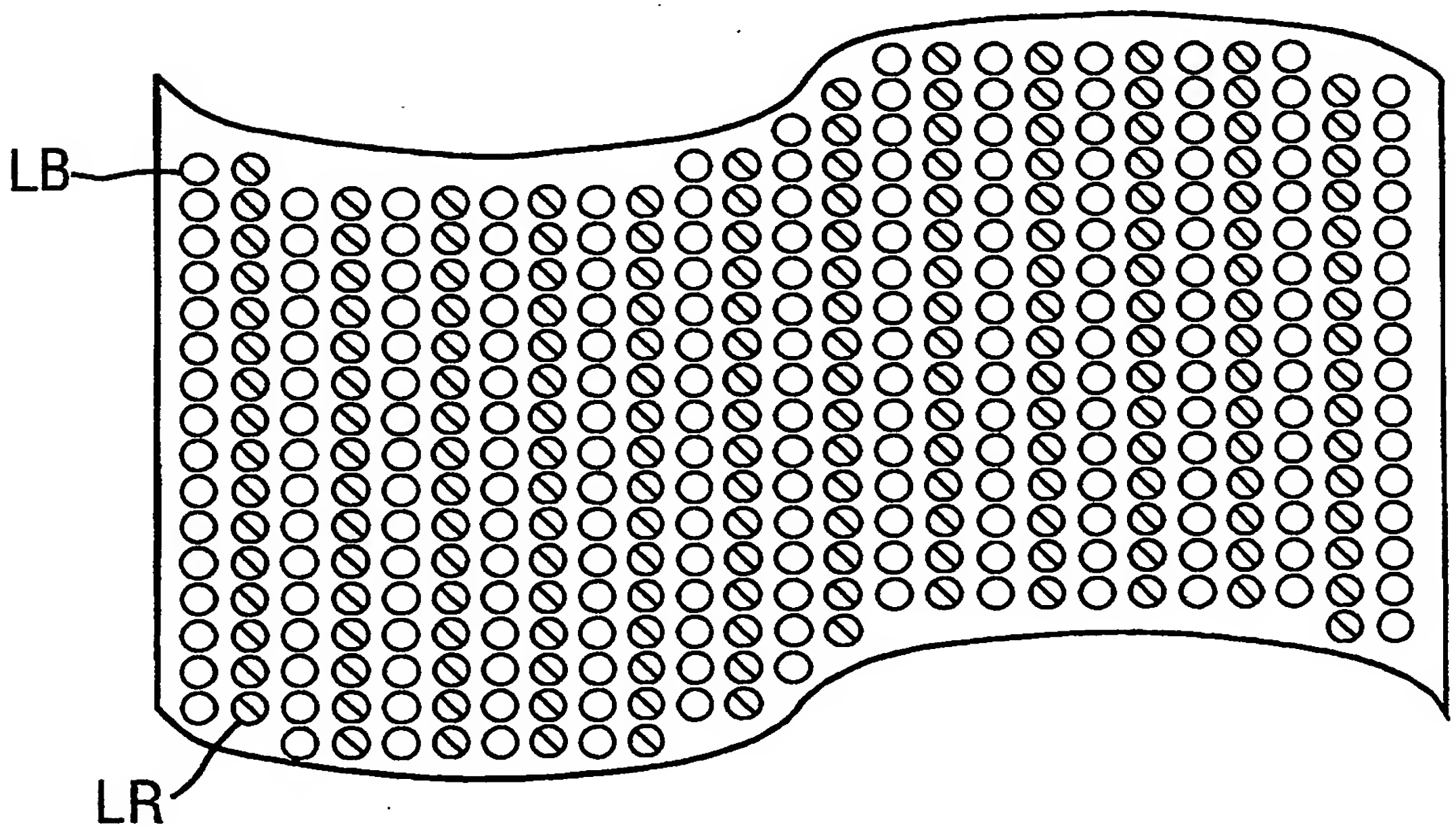


FIG. 26



THERAPEUTIC LIGHT SOURCE AND METHOD

The present invention relates to a non-coherent light source for use in therapy such as photodynamic therapy (PDT), particularly using light emitting diodes (LED's).

5 Photodynamic therapy involves the administration of a photosensitising drug to an affected area, and its subsequent irradiation with light - see for example 'The Physics of Photodynamic Therapy' by B C Wilson and M S Patterson, Physics in Medicine & Biology 31 (1986) April No. 4, London GB.

10 The document GB 2,212,010 discloses a therapeutic light source which uses an array of discrete LED's as an alternative to lasers or laser diodes. The output of the LED's is focussed so as to provide the necessary intensity.

15 The document WO 94/15666 discloses a therapeutic light source specifically for PDT, with an integrated array of LED's mounted on the distal end of a hand piece. The LED's are overdriven to give the necessary intensity, and cooled by the flow of water around a closed loop passing along the hand piece. The document US 5728090 discloses a somewhat similar device with various different types of head containing integrated LED matrices. These
20 devices require complicated liquid cooling circuits which would add to the cost of the device and add to the bulk of the hand piece, which is disadvantageous for invasive use.

The document US 5728090 mentions that the wavelength of the LED's is between 300 nm and 1300 nm and is selected based upon the
25 particular photosensitive dye used during PDT. However, the wavelengths of LED's capable of providing the necessary intensity for PDT cannot freely be chosen within that range.

According to one aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a non-planar array of

light-emitting diodes conforming with the shape of an external area to be treated or diagnosed.

According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising a first array of light-emitting diodes and a second array of light emitting diodes movably connected thereto.

According to another aspect of the present invention, there is provided a light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on the curved inner surface of a housing arranged to cover at least part of the length of a patient.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a sleeve so as to direct light onto part of an arm and/or hand of a patient when inserted into the sleeve.

According to another aspect of the present invention, there is provided a light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on the surface thereof an array of discrete light-emitting diodes.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an air-cooled array of LED's, the air being vented in the vicinity of the array. In one embodiment, the array is mounted at the distal end of a hand piece suitable for invasive therapy.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's coupled to a light

guide for delivering the light to the area to be treated. Preferably, the LED's are directly coupled without intervening optical devices.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with emission spectra substantially limited to the range 550 to 660 nm, and preferably to one of the
5 ranges 590 to 640 nm, 560 to 644 nm, 650 to 660 nm, and 550 to 570 nm.

According to another aspect of the present invention, there is provided a therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm, 470 nm, 505 nm or 525 nm.

10 Specific embodiments of the present invention will now be described with reference to the accompanying drawings, in which:

Figure 1 is a diagram of a parallel-series matrix of discrete LED's used in first and second embodiments of the present invention;

Figure 2 is perspective diagram of the first embodiment;

15 Figure 3 is a cross section of part of the first embodiment;

Figure 4 is a graph showing the variation of intensity in a cross-section of the output of the first embodiment;

Figure 5 is a cross-sectional diagram of a second embodiment;

Figure 6 is a cross-sectional diagram of a third embodiment;

20 Figure 7 is a cross-sectional diagram of a fourth embodiment;

Figure 8 is a cross-sectional diagram of a fifth embodiment;

Figure 9 is a graph showing the absorption spectrum of PpIX and the emission spectra of two examples of LED's suitable for use with the
embodiments;

25 Figures 10a and 10b are side and front views respectively of an LED array in a sixth embodiment for treatment of the face;

Figures 11a, 11b and 11c are a cross-section in the plane of the patient's arm, a top view and a vertical cross-section transverse to the patient's arm of an LED array in a seventh embodiment for treatment of the
30 elbows of a patient;

Figure 12 is a side view of an LED array in an eighth embodiment used for treatment of the foot or feet;

Figure 13 is a side view of an LED array in a ninth embodiment used for treatment of the lower leg;

5 Figures 14 and 15 show arrangements of an LED array in tenth and eleventh embodiments for treatment of respectively the face and a section of a patient lying on a bed;

10 Figures 16a and 16b show respectively front and side views of a set of similar LED arrays in an twelfth embodiment for treatment of one side of a patient;

 Figures 17a and 17b show respectively front and side views of an LED array in a thirteenth embodiment for treatment of a section of one side of a patient;

15 Figures 18a and 18b are respectively side and end views of a set of similar LED arrays in a fourteenth embodiment, for treatment of one side of a patient lying down;

 Figures 19a and 19b are respectively side and end views of an LED array in a fifteenth embodiment for treatment of a section of a patient lying down;

20 Figures 20a and 20b are top and side views respectively of an arrangement of LED arrays in a sixteenth embodiment for treatment of the face and/or scalp;

25 Figure 21 shows a similar arrangement to that of Figures 20a and 20b, in a seventeenth embodiment for treatment of the face and/or scalp of a patient lying down;

 Figures 22a, 22b and 22c show respectively a side view, a transverse cross-section and a longitudinal cross-section of an LED array arranged within a sleeve in an eighteenth embodiment, for treatment of the hand, forearm and/or elbow;

Figures 23a, 23b and 23c show respectively two different shapes of flexible LED array, and a flexible array applied as a patch onto the skin of a patient, in an nineteenth embodiment;

5 Figure 24 shows an LED array arranged on the side of a cylindrical intraluminal probe in a twentieth embodiment;

Figure 25 shows an LED array arranged on the surface of a spherical intraluminal probe in a twenty-first embodiment; and

Figure 26 shows a more specific example of the flexible LED array in the nineteenth embodiment.

10 In a therapeutic light source in the first embodiment, as illustrated in Figures 1 to 5, light is emitted from a parallel-series matrix of LED's L connected through a current-limiting resistor R to a source of a voltage +V. The LED matrix is mounted on a heatsink array H parallel to and spaced apart from a fan array F by support rods R. Air is blown by the fan array F onto the
15 back of the heatsink array H.

As shown in more detail in Figure 3, the heatsink array H comprises a plurality of individual heatsinks h mounted on the ends of the legs of the LED's, which pass through a support plate P. Each leg is soldered to an adjacent leg of another of the LED's in the same column. The support plate P
20 is perforated to allow air to flow more freely around the heatsinks h and the LED's L.

The LED's L are arranged so as to produce a substantially uniform illumination of $\pm 10\%$ or less across a treatment field by selecting the beam divergence and spacing of the LED's L so that their individual beams overlap
25 without causing substantial peaks or troughs in intensity. In the example shown in Figure 4, uniformity of $\pm 6\%$ is achieved. In this embodiment, no optical system is needed between the LED's and the patient; instead, the light is emitted directly from the LED's onto the patient. As the light is not concentrated by any optical system, the LED's have individual power outputs
30 of at least 5 mW and preferably at least 10 mW, to give the necessary fluence

rates in the treatment field of at least 30 mW/cm^2 in the red region of the spectrum and at least 10 mW/cm^2 in the blue region.

In one specific example, a 15 cm diameter array of 288 'Super flux' LED's was used to produce a total light output of 8 W at 45 mW/cm^2 in the treatment field. The LED's were driven at a higher current load than their specification while being cooled by forced air convection from the fans F. In the specific example, the current was limited to 90 mA per column of diodes, but may be increased to 120 mA or more if increased light output is needed. The number of diodes in series, in each column, is selected so that the total forward operating voltage is as close as possible to, but less than, the power supply output voltage, in this case 48 V. This arrangement avoids wasteful in-circuit heating and maximizes the operating efficiency of the electrical system.

A method of treatment for oncological and non-oncological skin diseases such as cases of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas), viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism, using the first embodiment, will now be described. A cream or solution containing a photosensitising drug such as 5-ALA is applied topically under medical supervision to the affected area of the skin of the patient, or administered intravenously or orally. In another method of application for large areas, the patient may be immersed in a bath of solution. The affected area may then be covered for a period of 3 to 6 hours, or up to 24 hours if the treatment is to be continued the next day, to prevent removal of the drug and carrier, or activation by sunlight. The area is then uncovered and exposed to light from the lamp according to the first

embodiment for a period of 15 to 30 minutes. The treatment may then be repeated as necessary, for a total of 1 to 3 treatments. This method is particularly suitable for the treatment of patients with very large lesions or multiple lesions extending over a large area.

5 In a method of treatment using the device of the first embodiment, the LED array is positioned approximately parallel to an external affected area of a patient to be treated, with a separation sufficient to achieve the uniform illumination as shown in Figure 4, for example 2 to 5 cm. The device may also be used for cosmetic or partially cosmetic treatment with a
10 photosensitizing drug for portwine stain removal and hair restoration/removal, and without a photosensitizing drug for skin rejuvenation, wrinkle removal or biostimulation (including wound healing).

The lamp may also be used for fluorescence detection (photodiagnosis).

15 The first embodiment may be modified in a second embodiment, as shown in Figure 5, by the addition of a frusto-conical waveguide W, for example of acrylic (e.g. Perspex™) or glass, supported by the support rods R, which are extended in this embodiment. The waveguide W is arranged to concentrate light emitted by the LED's onto a smaller area with higher
20 intensity. This arrangement is suitable for treating smaller external surfaces.

The second embodiment may be modified in a third embodiment, as shown in Figure 6, to deliver the light from the waveguide W into a lightguide L for internal treatment. The lightguide L, such as an optical fibre or fibre bundle, or liquid light guide, is held in a lightguide receptacle or adapter A,
25 that is compatible for example with Olympus, Storz, ACMI or Wolf light cable fittings, in abutment or immediately adjacent relation with the narrow end of the waveguide W. The lightguide L may be of 3, 5 or 8 mm diameter. The support rods R align the optical axes of the waveguide W and lightguide L, so that the light emitted by the waveguide W is launched into the lightguide
30 L. In the third embodiment, the light is concentrated by the waveguide and

emitted over a small area at the distal end of the lightguide L which may be inserted into body cavities for oral, gynaecological, gastrointestinal or intraluminal treatment.

The third embodiment may be modified in a fourth embodiment, as shown in Figure 7, in which the discrete LED array is replaced by an integrated multi-die LED matrix IM (for example part no. OD 6380, OD 6624 or OD 6680 available from AMS Optotech, Bristol, UK) mounted on the support plate/heatsink P, H. A Peltier effect thermoelectric cooler PC is mounted in thermal contact with the opposite side of the support plate P, the heated side of which is cooled by the fan F. The proximal end of the lightguide L is directly adjacent or abutting the integrated LED matrix IM, which are of similar cross-section so that the waveguide is not needed to launch the emitted light into the lightguide L.

A fifth embodiment, as shown in Figure 8, is designed specifically for treatment of the cervix, such as PDT treatment. The fifth embodiment has the form of a hand piece having a hollow stem S, for example of acrylic or polycarbonate, through which air is blown at low pressure by a fan F mounted at the proximal end. The distal end has a head portion HP comprising a housing within which is mounted a discrete LED array mounted on a support plate/heatsink P/H. Air passes through the hollow stem S onto the heatsink H so as to extract heat therefrom and is then vented through apertures AP on the proximal side of the housing. The distal end of the housing is concave and dimensioned so as to fit closely over the end of the cervix C. A transparent end window W, for example of acrylic or glass, prevents infiltration of the LED's. Power is carried to the LED's through wires (not shown) mounted on the wall of the acrylic stem S. In use, the hand piece is positioned so that the distal end fits over the cervix of the patient and is clamped in position for the duration of the treatment.

The selection of appropriate discrete LED's for PDT using any of the first to fourth embodiments will now be described, grouped according to die material.

A first suitable type of LED is based on aluminium indium gallium phosphide/gallium phosphide (AlInGaP/GaP) of transparent substrate (TS) or absorbing substrate (AS) type. The output wavelengths are in the range 590 to 640 nm with peak emission wavelengths of 590, 596, 605, 615, 626, 630 and 640 nm. Commercially available examples are the 'SunPower'TM or 'Precision Optical Power'TM series from Hewlett Packard Company, designed for use in the automotive industry, for commercial outdoor advertising and traffic management. Suitable LED's are those packaged as: SMT (surface mount technology) e.g. HSMA, HSMB, HSMC, HSML series and preferably HSMB HR00 R1T20 or HSMB HA00R1T2H; Axial e.g. HLMA or HLMT series; T1 e.g. HLMP series, preferably HLMP NG05, HLMP NG07, HLMP J105; T13/4 e.g. HLMP series, preferably HLMP DG08, HLMP DG15, HLMP GG08, HLMP DD16; SuperfluxTM e.g. HPWA or HPWT series, preferably HPWA (MH/DH/ML/DL) 00 00000, HPWT (RD/MD/DD/BD/RH/MH/DH/BH/RL/ML/DL/BL) 00 00000, most preferably HPWT (DD/DH/DL/MH/ML/MD) 00 00000; SnapLEDTM e.g. HPWT, HPWS, HPWL series, preferably HPWT (SH/PH/SL/PL) 00, HPWT (TH/FH/TL/FL) 00 or HPWS (TH/FH/TL/FL) 00. Suitable products from other manufacturers include: of SMT type, Advanced Products Inc. (API) part no. HCL4205AO; of T1 type, American Bright Optoelectronics (ABO) part no. BL BJ3331E or BL BJ2331E; of Superflux type, ABO part no.'s BL F2J23, BL F2J33 and BL F1F33.

A second suitable type of LED is the aluminium indium gallium phosphide/gallium arsenic (AlInGaP/GaAs) type, with emission wavelengths in the range 560 to 644 nm and peak emission wavelengths of 562 nm, 574 nm, 590 nm, 612 nm, 620 nm, 623 nm and 644 nm. Examples commercially available from Toshiba in T1 package are the TLRH, TLRE, TLSH, TLOH or

TLYH series, preferably TLRH 262, TLRH 160, TLRE 160, TLSH 1100, TLOH 1100, TLYH 1100 or S4F4 2Q1; or in T13/4 package are the TLRH or TLSH series, preferably TLRH 180P or TLSH 180P. Another example is Kingbright L934SURC-E.

5 A third suitable type of LED is aluminium gallium arsenic type (AlGaAs), with emission wavelengths in the range 650 to 660 nm. Examples in T1 package include the Toshiba TLRA series, preferably TLRA 290P or TLRA 293P, and Kingbright L934 SRCG, L934 SRCH, and L934 SRCJ and in T13/4 package include Kingbright L53 SRCE.

10 A fourth suitable type of LED is gallium phosphide (GaP) type, with emission wavelengths in the range 550 to 570 nm.

 A fifth suitable type of LED is indium gallium nitride (InGaN). In the type with an emission wavelength of 525 nm, commercially available examples include: in SMT package, API's HCL 1513AG; and in T1 package, 15 Farnell's #942 467, Radio Spare's #228 1879 and #249 8752, API's HB3h 443AG and Plus Opto's NSPG500S. In the type with emission wavelengths of 470 and 505 nm and T1 package type, examples are Farnell's #142 773, Radio Spare's #235 9900 and American Bright Optoelectronics Inc.'s BL BH3PW1.

20 A sixth suitable type of LED is gallium nitride/silicon (GaN/Si), with an emission wavelength of 430 nm. One commercial example is Siemens LB3336 (also known as RS #284 1386).

 Each of the above LED types is selected to have an emission spectrum substantially coincident with the absorption spectrum of one or more of the following common photosensitizers given below in Table 1, and therefore 25 embodiments having such LED's are suitable for PDT. For example, Figure 9 shows the absorption spectrum of PpIX, including peaks at 505nm, 545 nm, 580 nm and 633 nm. Inset are the emission spectra, in units of peak intensity and on the same wavelength axis, of LED part no. HPWA DL00 with a peak at 590 nm and LED part no. HPWT DH00 with a peak at 630 nm, the peaks

having sufficient breadth to give a substantial overlap with the 580 nm and 633 nm peaks respectively in the absorption spectrum of PpIX.

Table 1

Photosensitizer	Red absorption Band (nm)	Red Peak (nm)	Blue/Green Peak (nm)
Naphthalocyanines	780-810		
Chalcogenopyriliun dyes	780-820		
Phthalocyanines (e.g. ZnII Pc)	670-720	690	
Tin etiopurpurin (SnET ₂)	660-710	660-665	447
Chlorins (e.g. N-Aspartyl chlorin e6 or NPe6)	660-700	664	
Benzoporphyrin derivative (BPD)		685/690	456
Lutetium texaphrin (Lu-Tex)		735	
Al(S ₁ /S ₂ /S ₃ /S ₄) Pc	660-710	670/685	410, 480
Photofrin		625/630	405
Protoporphyrin IX (PpIX) - from 5/ δ Aminolaevulinic Acid (5ALA)		635	410, 505, 540, 580
Tetra m-hydroxyphenyl Chlorin (mTHPC)		650	440, 525

5

The discrete LED array may comprise more than one different type of LED, each with different emission spectra, selected to match different absorption bands of the selected photosensitizer. Each type of LED may be switched independently. The penetration depth (i.e. the depth at which the intensity has been attenuated to e^{-1}) may also be varied by switching on only one type of LED in the array so as to select a suitable emission band, since the penetration depth is a function of the wavelength.

10

The LED array may be composed of individually switchable spatially distinct segments of LED's. Selected segments may be switched on so as to treat a selected area of the patient within the overall area of the matrix array.

5 The lamp may include an electro-optical detector arranged to monitor the light dose delivered and to switch off the light emission when a target dose is reached. Alternatively, or additionally, the detector is arranged to monitor the instantaneous light intensity and to vary the electrical power supplied to the tubes so as to maintain the intensity within predetermined limits, and/or to switch off the light emission if a maximum limit is exceeded.

10 Various different arrangements of LED array suitable for treatment of different areas of a patient will now be described. The LED's are discrete LED's as described above. Except where stated otherwise, the LED's may be fan-cooled using integrated fans.

15 Figures 10a and 10b show an array of LED's L in a sixth embodiment, arranged on a support P shaped as a curved visor for treatment of the face of a patient. The array is supported in front of the patient's face by a head band HB or other head wear worn by the patient.

20 Figures 11a to 11c show an array of LED's L in a seventh embodiment arranged within a cuboid housing HO which has two similar apertures AP on one face, to allow the elbows to be inserted into the housing HO. The edges of the apertures AP are cushioned to allow the arms to be rested comfortably. Within the housing HO is arranged a surface SU which is curved both in the plane of the arms and perpendicular to that plane, as shown in Figure 11c. The LED's L are mounted on this surface SU so that light emitted therefrom is
25 concentrated onto the elbows of the patient.

Figure 12 shows an LED array L in an eighth embodiment mounted on a support plate P, and covered by a transparent or translucent cover on which the foot or feet of the patient rest during treatment.

30 Figure 13 shows an LED array L in a ninth embodiment mounted on a support plate P and arranged for treatment of the lower leg of a patient.

Figures 14 and 15 show an LED array L, mounted in a housing HO in the form of a trapezoid prism, the upper inner surface carrying the LED array and the lower surface being open to allow light to fall onto the patient. The side faces may be reflective, or carry additional LED arrays. In the tenth embodiment shown in Figure 14, the housing HO is mounted at one end of a bed so that its height above the bed is adjustable, for facial treatment of a patient lying on the bed. In the eleventh embodiment shown in Figure 15, the housing HO is mounted on a stand ST and is adjustable in height, for treatment of a selected part of a patient lying on the bed.

Figures 16a and 16b show a series of four coplanar LED arrays L in a twelfth embodiment arranged to treat one side of a patient. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

Figures 17a and 17b show a single LED array L in a thirteenth embodiment positioned to treat a section of the patient.

Figures 18a and 18b show a series of three coplanar LED arrays L in a fourteenth embodiment arranged to treat one side of a patient lying down. Each of the arrays is independently switchable so that selected sections of the patient can be treated.

Figures 19a and 19b show an array of LED's L in a fifteenth embodiment mounted on the inner surface of a curved housing HO for treatment of a patient lying on a further, planar array of LED's, for treatment of a section of the patient from all sides. The housing HO is slidable along the length of the patient so as to treat a selected area of the patient. Sections of the planar array of LED's are switchable so as to illuminate only the selected section.

Figures 20a and 20b show a sixteenth embodiment comprising a front-facial LED array L_F for directing light onto the face of the patient from the front, a scalp LED array L_S and left and right side-facial LED arrays L_L , L_R moveably connected, for example by hinges, to the front-facial array L_F , for

directing light onto the scalp, left side of the face and right side of the face respectively. The front-facial array L_F is slideably attached to a stand ST for vertical adjustment to the head height of the patient, preferably when sitting.

Figure 21 shows a seventeenth embodiment, similar to that of Figures 20a and 20b, except that it is arranged for facial and/or scalp treatment of a patient when lying down. The stand ST is mounted on a bed, instead of being free-standing, and the arrays are rotated by 90° so as to correspond to the position of the patient's head when lying down.

Figures 22a, 22b and 22c show an eighteenth embodiment in which an LED array L is mounted on the inner surface of a sleeve SL so as to direct light onto the hand, forearm and/or elbow within the sleeve.

Figures 23a and 23b show respectively a square and a rectangular LED array L in a nineteenth embodiment mounted on a flexible backing member FB which can be applied to an area of the patient to be treated, such as part of the forearm as shown in Figure 23c, with the LED's facing inwardly. The LED array thereby follows the contours of the area to be treated. The flexible backing member FB may be cooled by a fan which is either discrete or connected thereto by a flexible membrane which is fixed around the flexible backing member FB and directs air from a fan onto the backing member, through which the air is vented.

Figure 24 shows an LED array in a twentieth embodiment arranged on the surface of a cylindrical intraluminal probe, while Figure 25 shows an LED array in a twenty-first embodiment arranged on the surface of a spherical head of an intraluminal probes. The probes are dimensioned for vulval, cervical, endometrial, bladder, gastrointestinal, oral, nasal, aural and/or bronchial treatment.

In tests performed by the inventor, the efficacy of PDT using red (approximately 630 nm) emission from LED's was established in *in-vivo* comparative studies using a sub-cutaneous mammary tumour regrowth delay assay. Using radiobiological end-points, it was shown that the solid-state

prototype efficacies were comparable to that of expensive conventional lasers for PDT (i.e. no significant difference, $p=0.21$). These results were confirmed in further clinical studies in the treatment of Bowen's disease and basal cell carcinomas where comparative complete response rates were achieved as compared to laser PDT.

Figure 26 shows a more specific example of the nineteenth embodiment, consisting of rows of blue LED's L_B interspersed with rows of red LED's L_R so as to form a discrete LED array composed of different types of LED as described above. The blue LED's L_B are switchable on and off together, independently of the red LED's L_R which are also switchable on and off together. In this way, red or blue illumination may be chosen according to the type of treatment and penetration depth required.

The blue LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 370 to 450 nm, and preferably 400 to 430 nm. This range is particularly suitable for the treatment of pre-cancerous conditions, in particular actinic keratoses.

The red LED's have an emission spectrum substantially (for example full width half maximum bandwidth) in the range 620 to 700 nm. This range is particularly suitable for the treatment of non-melanoma, such as basal cell or squamous cell carcinoma, or mycosis fungoides.

CLAIMS

- 5 1. A light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on a flexible backing, the array including light-emitting diodes of a first type having a first emission spectrum and light-emitting diodes of a second type having a second emission spectrum different from the first emission spectrum.
- 10 2. A light source according to claim 1, wherein said light-emitting diodes of the first type are independently switchable from said light-emitting diodes of the first type.
- 15 3. A light source according to claim 1 or 2, wherein said first emission spectrum is substantially in the range 370 to 450 nm.
4. A light source according to claim 3, wherein said first emission spectrum is substantially in the range 400 to 430 nm.
- 20 5. A light source according to any preceding claim, wherein said second emission spectrum is substantially in the range 620 to 700 nm.
- 25 6. Use of a light source according to any preceding claim, in the treatment of a pre-cancerous condition.
7. Use according to claim 6, wherein said pre-cancerous condition is an actinic keratosis.

8. Use of a light source according to any one of claims 1 to 5, for the treatment of a non-melanoma.
9. Use according to claim 8, wherein said non-melanoma is a basal cell or squamous cell carcinoma.
10. A light source for therapy and/or diagnosis, comprising a non-planar array of light-emitting diodes conforming with the shape of an external area of a patient to be treated or diagnosed.
11. A light source as claimed in claim 10, wherein said array is mounted on a head portion for attachment to the head of a patient.
12. A light source as claimed in claim 10, wherein said array is mounted on a flexible support for attachment to the external area.
13. A light source for therapy and/or diagnosis, comprising a first array of light-emitting diodes and a second array of light emitting diodes movably connected thereto.
14. A light source as claimed in claim 13, further including a third array of light-emitting diodes movably connected to the first array.
15. A light source as claimed in claim 14, further including a fourth array of light-emitting diodes movably connected to the first array.
16. A light source as claimed in any one of claims 13 to 15, arranged for treatment of the face and/or scalp.

17. A light source for therapy and/or diagnosis, comprising an array of light-emitting diodes mounted on the curved inner surface of a housing arranged to cover at least part of the length of a patient.
- 5 18. A light source as claimed in claim 17, further comprising an array of light-emitting diodes arranged for positioning beneath the patient.
- 10 19. A light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a housing, and an aperture allowing a part of the patient's body to be inserted into the housing, the array being arranged to direct light onto the part of the patient's body when inserted into the housing.
- 15 20. A light source for therapy or diagnosis of a patient, comprising an array of light-emitting diodes arranged within a sleeve so as to direct light onto part of an arm and/or hand of a patient when inserted into the sleeve.
- 20 21. A light source for therapy or diagnosis of a patient, comprising an intraluminal probe carrying on a surface thereof an array of discrete light-emitting diodes.
- 25 22. A light source as claimed in claim 21, wherein said surface is substantially cylindrical.
23. A light source as claimed in claim 21, wherein said surface is substantially spherical.

24. A light source for therapy or diagnosis, comprising an array of light-emitting diodes arranged to give an output intensity of at least approximately 10 mW/cm^2 in a treatment field, and means for cooling the diodes by forced air convection.
- 5 25. A light source as claimed in claim 24, arranged so that light from the light-emitting diodes is incident directly on the treatment field with a spatial intensity fluctuation of approximately 10% or less.
- 10 26. A light source as claimed in claim 24 or 25, wherein the diodes are thermally coupled to one or more heatsinks.
- 15 27. A light source as claimed in claim 24, wherein the diodes are mounted at the distal end of a passage for carrying the air from the proximal to the distal end.
28. A light source as claimed in claim 27, including a fan mounted at the proximal end of the passage.
- 20 29. A light source as claimed in claim 27 or claim 28, wherein the distal end is dimensioned so as to be locatable proximate the cervix of a patient such that light from the diode array is incident on the cervix.
- 25 30. A light source as claimed in claim 29, wherein the distal end is concave so as to fit over the cervix.
- 30 31. A light source for therapy or diagnosis, comprising an array of light emitting diodes coupled to light guiding means for delivering light emitted by the diodes to an area to be treated.

32. A light source as claimed in claim 31, wherein at least part of the light guiding means is tapered away from the diodes.
- 5 33. A light source as claimed in claim 32, wherein the light guiding means includes a tapered part which tapers away from the diodes so as to concentrate the light emitted by the diodes into a parallel-sided light guide.
- 10 34. A light source as claimed in claim 31, wherein the light emitting diodes are integrated in the array.
35. A light source as claimed in claim 34, wherein the diodes are thermally coupled to thermoelectric cooling means.
- 15 36. A light source as claimed in claim 34 or 35, wherein the light guiding means comprises a parallel-sided light guide coupled to the integrated array.
- 20 37. A light source as claimed in claim 33 or 36, wherein the parallel-sided light guide comprises one or more optical fibres and/or liquid light guides.
- 25 38. A light source for therapy or diagnosis, comprising an array of light emitting diodes having emission wavelengths substantially within the range 550 to 660 nm.
39. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 590 to 640 nm.

40. A light source as claimed in claim 39, wherein the diodes are of aluminium indium gallium phosphide/gallium phosphide die material.
- 5 41. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 560 to 644 nm.
42. A light source as claimed in claim 41, wherein the diodes are of aluminium indium gallium phosphide/gallium arsenic die material.
- 10 43. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 650 to 660 nm.
44. A light source as claimed in claim 43, wherein the diodes are of aluminium gallium arsenic die material.
- 15 45. A light source as claimed in claim 38, wherein the emission wavelengths are substantially within the range 550 to 570 nm.
- 20 46. A light source as claimed in claim 45, wherein the diodes are of gallium phosphide die material.
47. A light source for therapy or diagnosis, comprising an array of LED's with peak emission spectra of approximately 470 nm, 505 nm or 525 nm.
- 25 48. A light source as claimed in claim 47, wherein the diodes are of indium gallium nitride die material.

49. A therapeutic light source comprising an array of LED's with peak emission spectra of approximately 430 nm.
50. A light source as claimed in claim 49, wherein the diodes are of gallium nitride/silicon die material.
51. A light source as claimed in any of claims 10 to 50, wherein said LED's include a first set of LED's and a second set of LED's having different emission spectra from said first set.
52. A light source for therapy or diagnosis, comprising an LED array including a first set of LED's and a second set of LED's having different emission spectra from said first set.
53. A light source as claimed in claim 52, wherein the first and second set of LED's are independently switchable.
54. A light source for therapy or diagnosis, comprising an LED array including a first set of LED's and a second, spatially distinct set of LED's independently switchable from said first set.
55. Use of a light source as claimed in any one of claims 10 to 50 except for claims 29 and 30, and claims dependent thereon, for cosmetic treatment of a patient.
56. Use as claimed in claim 55, for photodynamic treatment of the patient.
57. Use as claimed in claim 56, for portwine stain removal, or hair restoration or removal.

58. Use as claimed in claim 55, for skin rejuvenation, wrinkle removal or biostimulation.
- 5 59. Use of a light source as claimed in any one of claims 10 to 54, for medical treatment of a patient.
60. Use as claimed in claim 59, for photodynamic treatment of a patient.
- 10 61. Use as claimed in claim 60, except when dependent on claim 29 or 30, in the treatment of one or more of actinic/solar keratoses, Bowen's disease, superficial basal cell carcinoma, squamous cell carcinoma, intraepithelial carcinoma, mycosis fungoides, T-cell lymphoma, acne and seborrhoea, eczema, psoriasis, nevus
- 15 sebaceous, gastrointestinal conditions (e.g. Barratt's oesophagus and colorectal carcinomas), gynaecological disorders (e.g. VIN, CIN and excessive uterine bleeding), oral cancers (e.g. pre-malignant or dysplastic lesions and squamous cell carcinomas),
- 20 viral infections such as herpes simplex, molluscum contagiosum, and warts (recalcitrant, verruca vulgaris or verruca plantaris), alopecia areata, or hirsutism.
- 25 62. A light source for therapy or diagnosis substantially as herein described with reference to and/or as shown in Figures 1 to 4, or Figure 5, or Figure 6, or Figure 7, or Figure 8, or Figure 9, or Figures 10a and 10b, or Figures 11a to 11c, or Figure 12, or Figure 13, or Figure 14, or Figure 15, or Figures 16a and 16b, or Figures 17a and 17b, or Figures 18a and 18b, or Figures 19a and 19b, or
- 30 Figures 20a and 20b, or Figure 21, or Figures 22a to 22c, or

Figures 23a to 23c, or Figure 24, or Figure 25, or Figure 26 of the accompanying drawings.



INVESTOR IN PEOPLE

Application No: GB 0030974.0

Examiner: Susan Chalmers
(Mrs)

Claims searched: 1-10

Date of search: 24 May 2001

Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R: REHR

Int Cl (Ed.7): A61N: 5/06

Other: ONLINE: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
E,X	WO 01/14012 A (RUSSELL) see Figures, page 5 line 24 to page 6 line 9, page 21 line 20 to page 22 line 29 and page 24 line 1 to page 25 line 12	1,2 at least
P,Y	WO 00/15296 A (LIGHT SCIENCES) see eg Figures 5-8, page 2 line 31 to page 3 line 9 and page 8 line 3 to page 10 line 6	1-9
X	WO 99/19024 A (VIRULITE) see Figures 13 and 14 and page 8 lines 15-20	1,2 at least
X	WO 98/43703 A (PRESCOTT) see especially page 5 lines 16-26, page 9 lines 16-26 and page 18 lines 4-25	1,2 at least
Y	EP 0266038 A (KUREHA) see photodiodes 3a,3b in Figures 1-3 and page 3 lines 32-40	1,3-5
X	US 5616140 (PRESCOTT) see parts 20,22,702,802 in the Figures, column 5 lines 1-10 and 54-62 and column 14 line 64 to page 15 line 9	1,2,5-9 at least

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